NIH R01

Grant Application Mentor

Social & Behavioral Sciences

Principal
Investigators
Association™

A Note from the Publisher

Dear Professional:

Thank you for ordering "NIH R01 Grant Application Mentor: Social & Behavioral Sciences" from the Principal Investigators Association Library. This resource is designed to help you better understand — and make the most of — your R01 grant application for Social and Behavioral Sciences to the National Institutes of Health (NIH).

Dr. Jo Anne Schneider served as author for this manual. Dr. Schneider is currently an Associate Research Professor in Anthropology at George Washington University. She served as an American Association for the Advancement of Science (AAAS) Science and Technology Policy Fellow at NIH working with National Cancer Institute to translate research into practice (2003-2005). Dr. Schneider is an urban anthropologist focusing on the role of government, non-profits, and communities in inter-group relations, opportunity structures for marginalized populations (immigrants, refugees, people of color, people with disabilities, low income families), and social welfare and health policy creation and implementation.

In addition to the special reports that make up the library, Principal Investigators Association offers NIH and NSF grant application manuals, and a year-long series of interactive webinars — all devoted to helping you improve performance and spend more time doing what you love: the research. Our goal as an association is to be the world's leading source of real-world, results-oriented information for our members in all fields of science. Our unique approach — delivering targeted guidance, case studies, success strategies and best practices — has earned us a reputation for depth, usefulness and high-value information as well as a loyal group of members who rely on that information to help them with their administrative and funding duties. We're glad you've joined them and invite you to review all of our products and services at www.principalinvestigators.org.

We are always on the lookout for interesting topics, researcher needs, and ways we can be of service to you. If you have a success story you would like to share with your colleagues, please do not hesitate to contact me. I would be delighted to hear from you, and I look forward to serving you and your organization with the best advice and information available in the future.

Best Regards,

Leslie Norins, MD, PhD
Retired Founder
Principal Investigators Association
9990 Coconut Road Suite 316
Bonita Springs, FL 34135
Info@principalinvestigators.org

Acknowledgements

Table of Contents

Color Key:

Throughout this report, we have used highlighted text to indicate the following:

☐ — original text by authors of this report
(no color)

🟥 — directly quoted NIH information
(pink)

🟨 — paraphrased NIH information
(yellow)

🟦 — directly quoted information from successful NIH grant applications
(blue)

Introduction

Applying for a National Institutes of Health (NIH) R01 grant is an involved process with many facets to consider and extensive guidelines to follow. This manual will guide you through the steps involved and help you submit the best proposal possible. This manual focuses on R01 grants for the social and behavioral sciences. This includes a broad range of projects coming out of the disciplines of Sociology, Anthropology, Psychology, Political Science, Urban Studies, and sometimes Economics, as well as applied disciplines like nursing, social work, public health, public policy, and communications. Social and Behavioral Science applications look different from biomedical or purely clinical proposals, although social or behavioral science techniques may be components of a multi-methods project involving both social science and biomedical or clinical elements. In addition to drawing material from NIH, the manual relies on interviews with program officers at Institutes that fund a large number of social and behavioral science proposals as well as social scientists who have written R01 applications and served on NIH review panels.

Of course, all research begins with an idea, and you must determine if yours should be funded by an R01 grant. Your research must meet NIH's priorities, but it is just as essential that the grant is the appropriate mechanism for your project.

Once you've verified that an R01 is right for you, you'll need to work out the specifics. Think about when to apply, what to title your proposal, and how to articulate your hypothesis. But before you actually begin, consider creating a writing schedule. Chapter 2 includes a sample timetable that will help you move through the steps of the application process more easily and manage your time effectively.

As you begin writing your proposal, remember the message you are trying to convey. You should explain your project thoroughly so readers will understand all

aspects of it. But you also want to tell a compelling story and entice reviewers to approve your research.

Several chapters of this manual help guide you through the writing process. They offer advice for developing your Project Summary/Abstract, Biographical Sketch, Environment section and Research Plan. They also help you ensure your Research Strategy addresses your project's Innovation, Significance, Approach and Overall Impact.

When considering your project costs, refer to our chapter on creating a budget. You may also need to consult the section detailing considerations for special agents and human subjects. Each chapter includes checks to ensure you're following NIH guidelines every step along the way.

Before you submit your application, take time to review it. Make certain you've included all the necessary components and adhered to all rules. You'll also need to correct any errors and remedy weaknesses before sending your proposal to NIH.

Once you've submitted your application, it goes through a comprehensive review. The final chapter of this manual delineates that process. It also explains what NIH scores mean and what steps you can take after you receive them. Finally, the guide includes a resource list of specialty guides available through NIH and PIA on developing your proposal. Several academic articles on developing your proposal are also included in the resource list.

Chapter 1:
Social and Behavioral Science R01s

Social and Behavioral Science Applications focus on a broad range of topics and use a diverse array of methods. NIH's Office of Behavioral and Social Science Research (OBSSR) defines social and behavioral research as:

Behavioral and social sciences research is a large, multifaceted field, encompassing a wide array of disciplines. The field employs a variety of methodological approaches including: surveys and questionnaires, interviews, randomized clinical trials, direct observation, physiological manipulations and recording, descriptive methods, laboratory and field experiments, standardized tests, economic analyses, statistical modeling, ethnography, and evaluation. Yet, behavioral and social sciences research is not restricted to a set of disciplines or methodological approaches. Instead, the field is defined by substantive areas of research that transcend disciplinary and methodological boundaries. In addition, several key cross-cutting themes characterize social and behavioral sciences research. These include: an emphasis on theory-driven research; the search for general principles of behavioral and social functioning; the importance ascribed to a developmental, lifespan perspective; an emphasis on individual variation, and variation across sociodemographic categories such as gender, age, and sociocultural status; and a focus on both the social and biological contexts of behavior.

The core areas of behavioral and social sciences research are divided into basic or fundamental research and applied research. The basic and applied research distinction serves more of an organizational function for purposes of this definition, rather than representing firm boundaries within the field. Indeed, many studies have both basic and applied components. Moreover, basic and applied research is often complementary. Basic research frequently provides the foundation for subsequent applied research, and applied research often influences the direction of basic research.

In general, social and behavioral science applications differ from biomedical proposals in that they tend to focus on broader and more complex questions than projects that explore a single set of chemical interactions, identify gene markers for a specific disease, or develop a computer model for disease development. While clinical trials also include social and behavioral science interventions, the process for understanding why a particular support system for caregivers or an evidence based intervention to reduce diabetes and obesity is different from a blind drug trial. This chapter outlines the kinds of social and behavioral science projects funded by NIH, which Institutes and Centers fund the most proposals of this nature, and provides some general tips for successful proposals.

THE R01 MECHANISM FOR SOCIAL AND BEHAVIORAL SCIENTISTS

An R01 project explores a specific research question than can provide insights into fundamental categories for health research or which provides insights on issues of public health, health disparities, health access, or clinical practice. A number of other topics can be explored through an R01, but to receive funding from NIH, the topic needs to meet a need expressed by NIH or address a critical health issue. R01s are not exploratory grants, but rather a mechanism to gather data on a specifically defined research question that is clearly defined as a gap in current knowledge or to test a research hypothesis or evidence based intervention. R01s are designed to build on prior research and investigators at the early stages of developing an idea should look at grant mechanisms designed for exploratory or pilot research like K awards, R03 or R21.

Since NIH is known for its biomedical and clinical research, social and behavioral scientists often believe that they have an uphill battle for funding. While social and behavioral science grants are still a small proportion of NIH grants, they are a growing part of the NIH portfolio. The broad range of methods used by social and behavioral scientists are increasingly understood and welcomed at NIH. However, social and behavioral scientists need to clearly explain how their research questions and methods contribute to the NIH enterprise. As Dr. Mark Luborsky and Dr. Andrea Sanker remind us, it is important for potential investigators to understand the cultural forces at NIH and see themselves as contributors to NIH's larger project of improving health and public health. [1]

---

[1] Luborsky, M. and Sanker, A. 2006. Cultural Forces in the Acceptance of Qualitative Research: Advancing Mixed Method Research. In Curr, L, Shield, R. and Wetle, T eds. Improving Aging and Public Health Research: Qualitative and Mixed Methods. Washington DC: American Public Health Association.

Who Funds Social and Behavioral Science Projects and How Many are Funded?

Social and behavioral science applications are less than 20 percent of the R01 grants funded by NIH each year, but both the absolute number of proposals and their percentage of funded projects has steadily increased in recent years. As table 1 demonstrates, social science grants were only 11 percent of successful proposals in 2001, but have been 17 percent of funded projects in the last two fiscal years. Funding for social science projects in fiscal year 2014 is 1.5 times the amount of funding from 2001, despite recent cuts at NIH. Funding for social and behavioral science projects has expanded while the overall amount of funding for NIH R01 grants has remained roughly the same over these fourteen years. This suggests that well designed social and behavioral science projects are welcomed at NIH.

Table 1: NIH R01 Funded Applications 2001, 2011-2015 (source NIH Reporter)

Fiscal Year	Projects	Total Funding	Social Science Projects	Total Funding	% Social Science
2001	6,754	$2,200,951,267	764	$284,238,684	0.11
2011	5,429	$2,307,395,380	811	$397,482,880	0.15
2012	5,367	$2,296,668,319	915	$461,823,653	0.17
2013	4,906	$2,045,111,857	849	$414,138,514	0.17
2014	5,030	$2,227,126,594	841	$429,970,501	0.17
2015	839	$371,724,028	3	$1,515,291	0.00
Total	21,571	$9,248,026,178	3,419	$1,704,930,839	0.16

To succeed, applicants need to clearly and concisely present an idea that fills a gap in existing research and has a measurable public health impact. This is true for any kind of grant, not just social and behavioral science projects. Table two gives the number of applications, the number of projects awarded funding, and the success rate for funding for all R01 applications from 2011-2015. Comparable information was not available for social and behavioral science projects. As table two demonstrates, only 14 to 15 percent of new applications are funded each year. The percentages are higher for applications that are continuations of ongoing projects (competing renewals), suggesting that it is even harder to get a new idea funded. As

documented in PIAs guide on resubmitting proposals that have been turned down (see *Revising and Resubmitting NIH Proposals* https://principalinvestigators.org/product/revising-and-resubmitting-nih-proposals-guide/), proposals that have been resubmitted after being turned down a first time also have a much better chance of funding. This means that researchers need to carefully develop their proposal if they are to have any hope of funding. They also need to be prepared to submit it several times before it is funded.

Table 2: Success Rates for R01 Applications 2011-2015 (source NIH Reporter)

Fiscal Year	2011		2012		2013		2014	
Grant Type	New	Competing Renewal	New	Competing Renewal	New	Competing Renewal	New	Competing Renewal
Applications	23,383	5,111	24,637	4,780	23,323	4,529	23,004	4,241
Awards	3,543	1,710	3,700	1,653	3,341	1,421	3,566	1,467
Success Rate	15%	33%	15%	35%	14%	31%	15%	35%

    To succeed, applicants need to clearly and concisely present an idea that fills a gap in existing research and has a measurable public health impact. This is true for any kind of grant, not just social and behavioral science projects. Table two gives the number of applications, the number of projects awarded funding, and the success rate for funding for all R01 applications from 2011-2015. Comparable information was not available for social and behavioral science projects. As table two demonstrates, only 14 to 15 percent of new applications are funded each year. The percentages are higher for applications that are continuations of ongoing projects (competing renewals), suggesting that it is even harder to get a new idea funded. As documented in PIAs guide on resubmitting proposals that have been turned down (see *Revising and Resubmitting NIH Proposals* https://principalinvestigators.org/product/revising-and-resubmitting-nih-proposals-guide/), proposals that have been resubmitted after being turned down a first time also have a much better chance of funding. This means that researchers need to carefully develop their proposal if they are to have any hope of funding. They also need to be prepared to submit it several times before it is funded.

Figures 1 and 2: Number of Grants Funded by Each Institute Overall and for Social Science
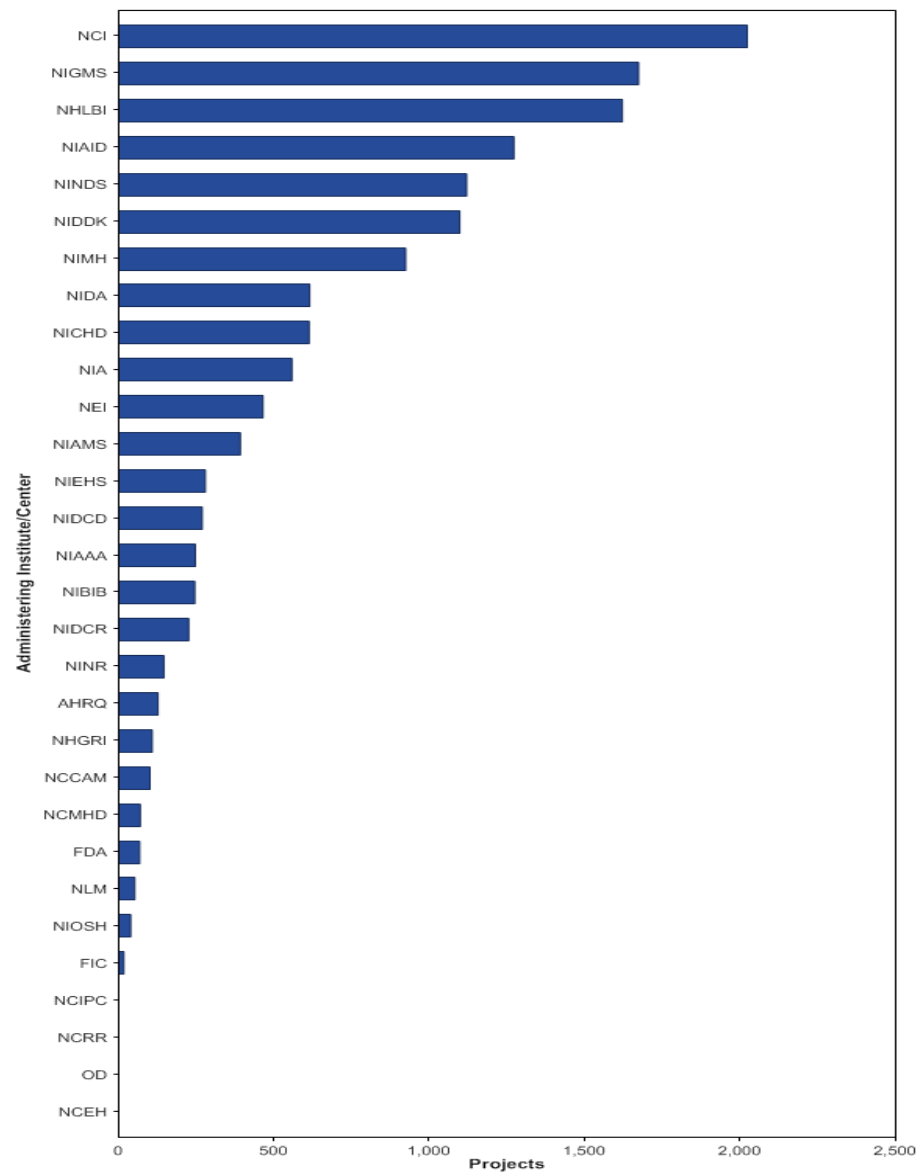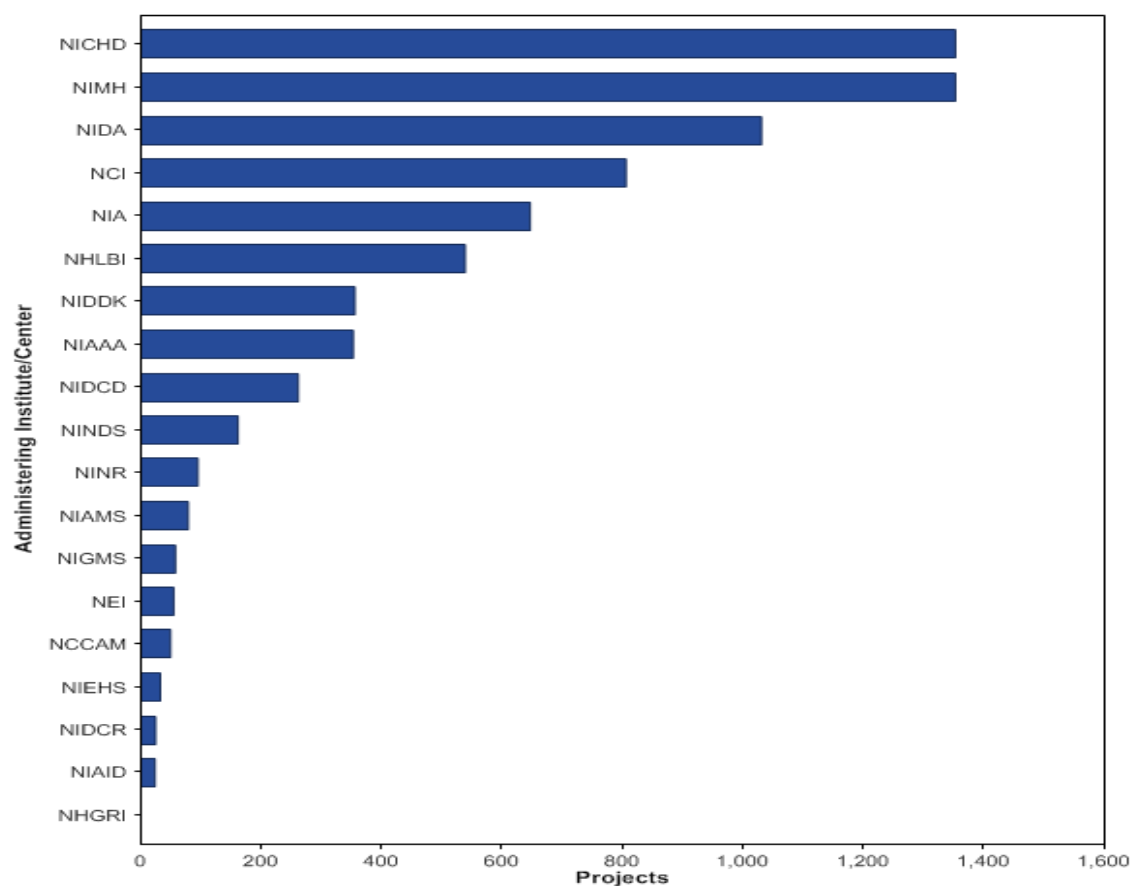
Figures 1 and 2 show the number of grants funded from 2011-2015 for each of the Centers that fund R01s. As these two figures demonstrate, the Institutes that fund the most grants overall are not the same ones that fund the largest number of social and behavioral science applications. NIGMS, with the most grants overall only funded 72 social and behavioral science proposals over this five year period. NCI, often considered the largest and most influential Institute is number two in the number of grants overall, but sixth in number of social proposals, with under 200 funded in the last five years.

National Institute of Mental Health (NIMH) funds many more social and behavioral science proposals (775), than any other Institute. This is unsurprising given its focus on mental health. However, as figure 2 and table 3 demonstrate, a wide range of Institutes fund social and behavioral science research. The bulk of proposals are funded by NIMH, NIDA, NICHD, NIA, NIAAA, NCI, NINDS, NHLBI, NIDDK, and NINR. Most of this guide will focus on the top six Institutes in number of social and behavioral science applications funded given there importance in funding social and behavioral science research.

That said, some of these Institutes and Centers have fewer social and behavioral research funded grants because they are smaller overall rather than because they are less interested in social and behavioral science projects. For example, National Institute on Nursing Research (NINR) and National Institute on Minority Health and Health Disparities (NIMHD) are relatively small Institutes which are friendly to social and behavioral science approaches.

While the top six Institutes have more money to give away, researchers should look at the whole range of Institutes when deciding which might be interested in their project. In some cases, you might consider asking that more than one Institute consider a proposal that responds to the priorities of both Institutes. In that way, you are dividing the amount of money requested from each and doubling your chance for funding. As with all applications, you should talk to appropriate program officers in each target Institute or Center to find out of this is a good idea.

As discussed in more detail in the next chapter, researchers need to first figure out what Institute would be most interested in their project. In order to figure this out, it is helpful to ask two questions:

1.   Does my research topic address the main mission and goals
       of this Institute or Center?
2.   Does this Institute or Center have a track record of funding
       social and behavioral science projects? Have they funded
       anything like my project in the past?

In order to answer these questions, researchers are encouraged to do research themselves on projects funded through NIH using the NIH reporter (http://projectreporter.nih.gov/reporter.cfm). While the tables and figures presented here looked at funding for social and behavioral research at all Institutes and Centers that use the R01 mechanism, researchers can do their own queries on particular Institutes of interest. Finding out that an Institute funds a significant number or proportion of grants on your topic would be a first step. Next, query the proportion of grants that use social or behavioral science methods. If they fund your topic and

appear to fund social and behavioral projects regularly, they would be an appropriate Institute to approach and explore their interest in funding your project.

Table 3: Number of Social Science Applications Funded by Institute/Center 2011-2015 (source NIH Reporter)

Administering Institute/Center	Projects	Total Funding
NIMH: National Institute of Mental Health	775	$403,203,869
NIDA: National Institute of Drug Abuse	488	$241,440,336
NICHD: Eunice Kennedy Shriver National Institute of Child Health and Human Development	388	$199,217,518
NIA: National Institute on Aging	294	$153,830,359
NIAAA: National Institute on Alcohol Abuse and Alcoholism	208	$94,098,036
NCI: National Cancer Institute	186	$99,024,477
NINDS: National Institute of Neurological Disorders and Stroke	182	$72,636,018
NHLBI: National Heart, Lung and Blood Institute	161	$102,811,144
NIDCD: National Institute on Deafness and Other Communication Diseases	138	$59,232,660
NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases	132	$68,452,224
NINR: National Institute on Nursing Research	104	$53,420,923
NEI: National Eye Institute	93	$36,322,485
NIGMS: National Institute of General Medical Sciences	72	$26,218,644
NIMHD: National Institute on Minority Health and Health Disparities	40	$15,519,245
NIEHS: National Institute of Environmental Health Sciences	37	$21,173,417
NCCIH: National Center for Complementary and Integrative Health	31	$16,075,360
NIAID: National Institute of Allergy and Infectious Diseases	27	$14,123,893
NIDCR: National Institute of Dental and Craniofacial Research	15	$8,565,947
NIBIB: National Institute of Biomedical Imaging and Bioengineering	13	$5,798,376
FIC: Fogarty International Center	10	$1,502,316
NIAMS: National Institute of Arthritis and Musculoskeletal and Skin Diseases	10	$5,858,678
NLM: National Library of Medicine	8	$2,973,950
NHGRI: National Human Genome Research Institute	6	$3,007,212
OD: Office of the Director (Crosscutting projects)	1	$423,752
Total	3,419	$1,704,930,839

What Kinds of Social Science Projects are Welcomed at NIH?

NIH funds a broad array of projects coming out of social and behavioral sciences. The important thing for a prospective applicant to remember when considering seeking funding from NIH is whether or not your project responds to a need in the health sciences that is of importance to the NIH and the Institute you hope will sponsor your project. As such, the first step involves exploring NIH priorities in the same way as someone doing biomedical or clinical research would

do. Successful applicants and peer reviewers interviewed for this manual stress that social and behavioral scientists need to get beyond their disciplinary concerns and look at how their research contributes to finding concrete answers to critical health issues. As one senior scientist who regularly reviews for NIH commented, "[Applicants need to] show that you are part of the general conversation about what needs to be known and have your [unique] way of doing [research]. We [social scientists] ask big, exciting, questions rather than [explore the] specific next minor step in brain imaging."

In general, social and behavioral science approaches can respond to one of several clear needs funded by NIH. Some social and behavioral science proposals provide general background research on critical health issues, exploring general population patterns, the ways health issues are understood by consumers or practitioners, the social categories of health and the dynamics of health access. On a more practical level, social and behavioral scientist provide data on why and how an intervention does or does not work. In either case, the research fills a gap in scientific or practical knowledge of a particular health problem. As such, social and behavioral science research can provide the categories needed to develop standardized measures or tools. Other examples of ways that social and behavioral scientists can contribute to the NIH mission include describing the environment for a particular health intervention, explaining how a target population for a public health initiative understands the issue, illuminating novel ways to implement evidence based health practices, or showing how caregivers go about juggling caregiving responsibilities and other aspects of their lives. These are only a few ways that social and behavioral science can contribute to NIH's mission.

The key is identifying a specific research topic that contributes to solving or understanding a concrete health issue of interest to NIH. Successful applications identify a compelling need and show how the research will meet that need throughout. For example, priorities mentioned by program officers that fund social and behavioral science proposals included:

- Public health oriented projects, emphasis on prevention and screening and what can be done in primary care to either prevent disease (screening) and careful follow up of survivors of serious illnesses.

- Service delivery to improve population health.
- Develop tools and questions about what people are perceiving. To quote one program officer: *"Measurement people need valid categories which social science can get at. The final product is new constructs, factors, dimensions that can be extended through further work."*
- Creating measures, critiquing existing measures.
- Focusing on psycho-social issues, but also physiological issues and risk.

 NIMH recently shifted its scientific approach to ask all applications to identify targets/methanisms of change. To quote a program officer:

- *On services or systems levels – what does this intervention do to manifest change? What is the unique target or mechanism that turns the key?*
- *Identify what it is that is the 'magic – or unique ingredient' that enhances child or adult mental health outcomes.*

Both program officers and researchers highlighted that social and behavioral science proposals usually have a stronger theoretical framework than most clinical and some biomedical studies. As such, these studies look at the fundamental theory that influences understanding the social determinants of disease and the effectiveness of interventions. For example, while at NIH, I developed a model to disseminate evidence based health interventions based on several social science theories and theories of the dissemination of innovation. This merging of theory and practice is particularly important in successful social and behavioral science proposals.

Social and behavioral scientists use a broad range of methods in their work. While quantitative studies are more familiar to many peer reviewers, NIH funds a wide range of methods, including qualitative research, multi-methods studies, economic research and social network analysis. While those conducting qualitative research still sometimes face challenges in the review processes, in recent years NIH and its reviewers have become more familiar with qualitative research. Sometimes reviewers ask for qualitative components. While researchers still need to ensure that reviewers are available that understand their methods, this is less of a problem now. That said, several program officers stated that they prefer multi-

methods projects to purely qualitative research. Methods and how to present them will be discussed in detail later in this manual.

NIH also welcomes a broad range of research topics, as long as they are related to NIH's primary mission of improving health and healthcare and its current specific goals. The same is true of the various Institutes and Centers that fund social and behavioral science research. The key to a successful proposal is defining a clear, measurable research question that solves a compelling health issue. The following are titles of social and behavioral science research projects funded as R01 projects from 2011-2015. They demonstrate a small portion of the range of current projects:

Project Title	Administering IC
DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES? http://projectreporter.nih.gov/project_info_description.cfm?aid=8468334	NHLBI
EXPLORING EXPERIENCES OF DISCLOSING HIV-POSITIVE STATUS WHILE IN PRISON http://projectreporter.nih.gov/project_info_description.cfm?aid=8465343	NIDA
A MOBILE PERSONAL HEALTH RECORD FOR BEHAVIORAL HEALTH HOMES http://projectreporter.nih.gov/project_info_description.cfm?aid=8495589	NIMH
STRESS-INDUCED MARIJUANA SELF-ADMINISTRATION: ROLE OF SEX AND OXYTOCIN http://projectreporter.nih.gov/project_info_description.cfm?aid=8561004	NIDA
UNDERSTANDING HOW PERSONAL NETWORKS CHANGE http://projectreporter.nih.gov/project_info_description.cfm?aid=8506360	NIA
FAMILY OUTCOMES IN AUTISM SPECTRUM DISORDERS http://projectreporter.nih.gov/project_info_description.cfm?aid=8524248	NIMH
SUBSTANCE USE IN RESERVISTS SOCIAL AND ENVIRONMENTAL INFLUENCES http://projectreporter.nih.gov/project_info_description.cfm?aid=8505856	NIDA
A RANDOMIZED CLINICAL TRIAL OF CULTURALLY TAILORED MI http://projectreporter.nih.gov/project_info_description.cfm?aid=8438022	NIAAA
THE AUTISM IMPACT MEASURE: A NEW TOOL FOR TREATMENT OUTCOME MEASUREMENT http://projectreporter.nih.gov/project_info_description.cfm?aid=8575724	NIMH
THE TIMES ARE CHANGING: A QUALITATIVE STUDY OF OLDER AND YOUNGER MARIJUANA USERS http://projectreporter.nih.gov/project_info_description.cfm?aid=8458476	NIDA
DISPARITIES IN CANCER SCREENING: THE ROLE OF MEDICAID POLICY http://projectreporter.nih.gov/project_info_description.cfm?aid=8562222	NCI
COMMUNICATION AND ECONOMIC OUTCOMES FOR CANCER SURVIVORS http://projectreporter.nih.gov/project_info_description.cfm?aid=8501827	NCI
NEIGHBORHOOD FACTORS AND CHILD MALTREATMENT: A MIXED METHOD STUDY http://projectreporter.nih.gov/project_info_description.cfm?aid=8558865	NICHD

These examples include broad brush explorations of the environment that impacts on health, such as the influence of neighborhood factors in child maltreatment and the role of parks and recreation departments in health disparities. Some explore family, work and other stressors on health issues like substance abuse or disclosing HIV status – a first step in ensuring treatment for people in prison. One explores the impact of public policy on prevention initiatives. In each case, the study shows how broader factors influence outcomes for health interventions.

Others provide specific background information needed to develop new tools and interventions. Exploration of how social networks change demonstrates the kinds of people resources that may be available to assist with a health problem and the influence of illness on social networks. Knowing how networks work helps providers developing interventions relying on social networks to understand what kinds of support is possible from the ill person's friends and family. Networks analysis combined with research on the impact of caregiving stress on those networks can show the potential outcomes of expecting members of a social network to provide support to someone who is ill. Likewise, exploration of the impact of autism on the family members of an autistic person or the impact of communication on cancer survivors shows how critical it is to take these factors into account in the treatment of these conditions.

Still other funded studies use social or behavioral science methods to implement or evaluate a new tool or intervention. This includes electronic health records, tools to measure the impact of autism on the person with a disability and his or her family, and clinical trials.

Several of these studies will be used throughout this guide as examples of strategies to write a successful proposal. Each share a clearly defined research question that meets a need for the Institute that funds it. In exploring whether NIH is the right funding source for your project, it is important to remember that R01s are not limited to a few types of studies like clinical trials or investigations of the social constructs behind a health condition. NIH Institutes will consider a broad range of projects. However, the project does need to clearly address a specific

health issue of interest at the present time with an innovative approach and clear outcomes. The remainder of this manual will outline ways to achieve this goal.

The Role of OBSSR

OBSSR was established in 1995 in the NIH Office of the Director to provide a centralized voice to promote social and behavioral science research at NIH. OBSSR's mission is:

(1) to integrate a behavioral and social sciences perspective across the NIH; (2) to disseminate behavioral and social sciences research findings; and (3) to provide advice to and communicate with the NIH Director, Congress, other government agencies, the research community and the general public on matters regarding behavioral and social sciences research.

OBBSR's role is to promote social and behavioral science research throughout NIH. As such, it does not usually directly fund research projects and is not a place to look for funding for your R01 project. However, OBSSR has joined with other Institutes to sponsor cross-cutting requests for applications on particular topics. For example, OBSSR is currently sponsoring a targeted R01 PAR-11-314 "Systems Science and Health in the Behavioral and Social Sciences (R01)" (see http://grants. nih.gov/grants/guide/notice-files/NOT-OD-14-122.html). These cross cutting Requests for Applications (RFA) are usually funded through other Institutes, but OBSSR usually plays a role in developing the review process for applications and selecting the final funded projects.

OBSSR has four core activities:

1. Developing and setting an agenda for national health research priorities in the social and behavioral sciences
2. Briefing the Director of NIH on progress related to behavioral and social science research and related issues
3. Promoting dialogue between social and behavioral scientists and the public
4. Training and career development for behavioral and social scientists

OBSSR's primary activities involve developing publications, conferences, educational materials, talks and other activities to improve behavioral and social science research on health issues. They also work behind the scenes to promote use of behavioral and social science research throughout the Institutes at the NIH. They develop forums and materials to explain findings from NIH sponsored behavioral and social science research to the general public and other scientists.

For a researcher looking for resources, OBSSR is a good place to look for background materials on research methods and cutting edge findings in the field. Generally, a researcher looking for funding for their grant would not contact OBSSR unless they were interested in a specific cross-cutting RFA developed by OBSSR. However, OBSSR may be able to suggest appropriate Institutes for a project if the researcher is having trouble identifying which Institute or Center might be interested in their topic.

Myths and Realities of Peer-review of Social Science Proposals at NIH

Many social and behavioral scientists believe that their proposals have a harder time getting funding at NIH because so many of the reviewers are biomedical or clinical scientists. While this may be true in some fields, increasingly NIH has developed review panels and lists of potential reviewers with a wide range of behavioral and social science expertise. Presuming that the applicant clearly outlines the methods and topics they plan to use and requests reviewers with this expertise in their cover letter, NIH will do its best to find appropriate reviewers. If the application is turned down because the reviewers did not have expertise in the topic or methods, this is grounds for automatic reconsideration of the proposal in the next round of reviews.

Given the diversity of social and behavioral science methods, the nature of the research questions, and the range of topics, social and behavioral scientists do need to do some extra work to present the case for their research. For example,

it is harder to explain how you will measure the impact of economic conditions on health access or the outcomes of a tool to identify stressors for families with an autistic child than to outline a series of experiments and their hypothesized outcomes. Methods sections need to provide more detail than in well-known biomedical experiments because many on the review committee may not be familiar with this kind of research. Cover letters are essential for behavioral and social science research, as this is where you explain the types of people who should review your work.

All of the seasoned reviewers, funded researchers and program officers interviewed for this guide mentioned that the biggest barrier for many social and behavioral science proposals is their expectation that they are going up against a biomedical scientific community that does not understand their work. Proposals that focus on explaining why social and behavioral science is generally important or spend a lot of time criticizing other methods or theoretical approaches are seldom funded. Your proposal is not the place to fight internecine battles within your discipline of theory or method.

Instead, social and behavioral scientists need to realize that they have been part of the research conversation for many years. While the goal of any proposal is to show how a research strategy fills a gap in current knowledge, it is best to explain how your project augments or builds on knowledge from other disciplines. A successful proposal will demonstrate knowledge of a research topic from a variety of disciplines, including biomedical research, and show how this research will advance knowledge or solve a particular health problem.

The remainder of this chapter briefly outlines how social and behavioral science applications are different than biomedical or clinical proposals. It offers some general tips for a successful proposal. The manual then provides detailed advice on developing various aspects of the application.

HOW IS A SOCIAL OR BEHAVIORAL SCIENCE APPLICATION DIFFERENT FROM A BIOMEDICAL PROPOSAL?

While all NIH proposals contain the same general elements, the content of a social and behavioral science application differs in many aspects from a biomedical or clinical proposal. The items to emphasize may differ and you will need to assemble a different kind of team than a biomedical proposal. The types of research partners and the supporting documents you need to collect from them will vary as well. Here are a few key elements to pay attention to when developing your proposal.

Different Aims, Goals, and Justifying Your Project

Whether you are exploring a big question like the impact of public policy on health care access or evaluating the implementation of an evidence based tool based on social or behavioral science measures, you need to clearly show that your project meets a specific need with measurable outcomes. Since social and behavioral science research project goals are often not as concrete as biomedical research, your proposal needs to show that you have identified a clear problem that can be studied in the time frame and resources of a three to five year research project. One senior researcher commented that many applicants "commit suicide by being all over the map in describing the problem or what they want to do." As Chapter 3 discusses in detail, a successful proposal clearly and concisely defines a problem, outlines related literature from all disciplines and demonstrates throughout how the proposed project will fill a gap in our knowledge or provide a concrete solution to this problem.

Likewise, aims need to be clearly stated and involve specific goals. If you normally do not use hypotheses in your research, it is helpful to present aims in similar language. The aims and goals need to be theoretically grounded and clearly linked to the research problem you present in your significance section.

The Kinds of People Necessary for a Successful Research Team Differ

Given the nature of social and behavioral science research, the key team members are likely to be more diverse than a laboratory project or a clinical trial. If your project uses multiple methods, you will need to include people with expertise in each of those methods on your team. While you may want to include senior, well-known researchers on your team to ensure that NIH knows your project has the track record to succeed, they may serve better as members of advisory committees than co-PIs. For more information on developing interdisciplinary team projects, see Principal Investigators Associations' guide, *Interdisciplinary Research Teams: The Scientist's Guide to Building Strong, Productive Teams* https://principalinvestigators.org/product/interdisciplinary-research-teams-guide/.

Often, projects involve clinical components or are hosted by community organizations. Staff at these organizations may be important to include on your research team. You may need more outside consultants to help with participant recruitment, media or web design for dissemination. Instead of hiring a few graduate students to work in a lab, your data collection and analysis staff may include clinicians, tape transcribers, experts at social network analysis or geographical information systems, and so forth. For example, one study of women's health hired a nurse practitioner as a key researcher to collect data. Studies based at hospitals or clinics will want a clinical staff person to serve as a co-PI or key team member to facilitate various aspects of the research and demonstrate the clinical applications of findings.

Your proposal will need to show that you have thought through what personnel need to be on your team and demonstrate how those people will help you successfully complete your project throughout the proposal. At the leadership level, this will involve bringing in key research staff with a range of needed skills and a track record of working together. Your proposal will need a discussion or chart showing how the various research team members will work together to complete the project. If team members cannot demonstrate prior experience collaborating on research, it may be helpful for those team members to perform some pilot research or publish a co-authored research article before submitting the proposal.

Given that some reviewers may not be familiar with social and behavioral science research, you may need to describe in some detail what each person will do and why it is important to include them. This is done in the bio-sketches, discussion of the data collection methods and analysis strategies, and the budget justification.

The Resources and Institutional Supports Needed for a Successful Project Differ

NIH looks at the resources of the university or institution hosting the research as much as it looks at the ability of the researchers to carry out the project. This involves both having the facilities to do the project and providing the researcher with sufficient support to do their work. In a biomedical study, the institutional resources section focuses on laboratories, equipment, and other materials needed to carry out the project. Social and behavioral science projects may also need concrete resources like office space, lab rooms to conduct interviews and focus groups, computers with specialized software, and other equipment. However, these resources are not the only things to include in a social science proposal. For social and behavioral scientists, institutional resources that provide access to research communities like a hospital or university outreach projects to a specific neighborhood with the target population may be more important. A functional human subject review system is also vital for any project involving specific people as research participants. Adequate libraries and access to national data sets are also important institutional supports. Your proposal will need to document these resources in their institutional resource statement.

One of the key supports a university or other institution needs to give a social or behavioral science researcher is time and a commitment to facilitate carrying out the project. If the university or institution has a medical facility or outreach project in a local community, they need to demonstrate that appropriate staff will facilitate the PI gaining access to research subjects through their facilities. Reviewers will look for concrete commitments for course releases or other research buy-outs to ensure that the researcher has the time to complete the project. If the project

involves using students in service learning classes to complete parts of the research, the institution needs to show that those classes will take place. Service learning courses are for credit classes that use actual research or service projects as part of the class work. For example, students in a research methods class may collect data, or students in a public health course may observe a clinic and write up their observations as their class paper.

Another resource that needs to be documented by the institution is access to people resources to help complete the project. This may involve committing graduate assistant to a project and covering part of their costs. If the university or institution has a center that conducts statistical analysis, provides GIS services, or has other resources needed by the project, letters indicating center staff willingness to participate in the project may be important to include.

Any project that involves a medical facility or community organization outside of the PI's institution will need to demonstrate that these institutions are willing to participate in the project and have the resources in the form of facilities and staff to be part of a project. For example, a project involving a community clinic will need to provide a support letter indicating their willingness to host the project and identify staff that will participate in it. They will also need to demonstrate they have the resources to participate. For example, if a project plans to use medical records from a clinic, but those records are incomplete and only on paper, the project will have difficulty carrying out the research. If clinic staff are supposed to present opportunities to participate in a smoking cessation intervention to appropriate patients, but they are disinterested in the project and too busy to mention it, the researcher will have a hard time finding participants. Researchers need to clarify what kinds of support they will need from community organizations hosting research and document that they have that support in their application.

Methods Differ and the Ways to Explain Them to Reviewers also Differ

Since the review panel will include biomedical researchers and clinicians likely to be unfamiliar with social and behavioral science methods, applicants will need to take extra care to explain their methods. As discussed in Chapter 5, researchers may need to use more detail in describing their methods than a biomedical proposal. Another common strategy may include using references to methods articles or texts as documentation of the efficacy of methods.

While reviewers can usually clearly see how a particular experiment will prove or disprove the aim of a biomedical project, the relationship between social and behavioral science methods and the aims of the project may be less clear. Each discussion of methods needs to be clearly tied back to the aims and initial research question, showing how this method will provide important data to answer the research question or demonstrate solutions to a specific health problem.

Program officers and peer reviewers interviewed for this manual highlighted that multi-methods are often beneficial in social and behavioral science projects. Applicants will both need to explain multiple methods and show how each method contributes to answering the research question. Proposals using several methods will also need to include a clear research plan which shows how data from different methods are related to each other, when each component will be collected, and how findings from different methods will be synthesized into the final product.

Researchers should never use appendices to expand on their research methods. However, many social and behavioral researchers will need to use the appendices to include research protocols like questionnaires and interview guides for focus groups or in-depth interviews. These materials will need to be prepared in advance or outlined for inclusion in the proposal.

Pilot Studies and Other Supporting Research also Need to Be Produced and Presented Differently

R01 projects are not the place to explore a research topic for the first time. These applications need to build on earlier research conducted by the researcher or others. Pilot studies use a small number of subjects to explore the research question. They show that the project is feasible and suggest potential outcomes. Since collecting pilot data takes time and is expensive, PIs who want to do R01 research must often think ahead several years in order to complete pilot studies and publish the results. This may include seeking funding through the PIs institution, other sources, or other mechanisms at NIH designed for exploratory research like the R21 or R03.

Presenting pilot data may be tricky. While the pilot needs to demonstrate that the research can be conducted and indicate some potential findings, it cannot be large enough to suggest that the research has already been done. The proposal needs to clearly show that the pilot leaves unanswered questions that need to be answered through a larger research study.

Researchers may also use data from related studies conducted by themselves or others instead of pilot data. For example, a researcher who has explored caregiving strategies for children with autism among children associated with a single specialized school may want to expand to children in an array of public and private schools or in another state or city. The data from the study in the single school would serve as pilot data. Multi-site studies of health care systems may propose extending work done by an advisor or member of the research team in another state. In this case, the researcher should present how the new data will expand on earlier research.

The Role and Risks to Human Subjects Differ Significantly from Biomedical Projects and Need to Be Explained in a Different Way

Unless the project uses deidentified data collected by someone else or involves study of policy, a social and behavioral science research project will need to be reviewed by its institution's human subjects review committee (IRB) before it begins. As discussed in Chapter 6, NIH will want to know that you have thought through the risks to human subjects in your study and have an adequate IRB committee available to review the proposal. The project will not need IRB approval before it is funded.

The potential risks of a medical procedure or new medication may be clear to a researcher, but a social or behavioral science project can create a number of additional risks. Will discussion of certain subjects create emotional problems for participants? Will participation in a project identify participants as belonging to a minority group or having a particular disease that may cause stigma in their community? Will an intervention take time away from work or other essential activities, harming participants' quality of life? What if data from the project was leaked, could it result in participants losing jobs, insurance, or something else they need? Social and behavioral science proposals need to outline each of these types of risks and explain why it is important to do the project anyway. For more information on developing human subjects review applications for social and behavioral scientists, see Principal Investigators Associations' guide *Qualitative Research & IRB: A Comprehensive Guide for IRB Forms, Informed Consent, Writing IRB Applications and More*
https://principalinvestigators.org/product/qualitative-research-irb/.

NIH encourages expanding medical research to include people from different racial and ethnic groups, women, and other marginalized populations often left out of health studies. Social and behavioral science projects are often seen as having the contacts to reach these kinds of populations. In addition, studies increasingly include populations that may not be in a position to make decisions for themselves like people with intellectual disabilities, autism, dementia, children or prisoners.

Regardless of the nature of the special population, the applicant will need to fill out forms that show that they have included these populations or explain why they are not included. For protected populations (pregnant women, children, prisoners, people with impaired decision making ability) special human subjects review will also be required. These elements will need to be included in the proposal's sampling plan, human subjects statements, and forms of various special populations.

The Physical Resources Needed to Carry Out the Project are Completely Different

Rather than labs and specialized equipment, social and behavioral science projects need completely different physical space. At the host institution, this will include office space, conference rooms, interview rooms, and places to securely store data and mobile equipment like tape recorders and laptops. The project may also require specialized printers, software, media equipment and studios, or access to statistical centers or GIS labs. These resources will need to be carefully planned and outlined in the institutional resource section, budget, and budget justification. These elements will be discussed in Chapter 7.

Partnerships with research sites are particularly important for social and behavioral science projects. In addition to willingness to host a project, a host site may also need to reserve workspace, office space, or secure filing cabinets to store data or research materials. These facilities and partnerships should be outlined in the research plan. Assurances that these resources will be available should be included in support letters from host sites.

Investigators Need to Pay Particular Attention to Which Panel Reviews Their Application, the Branch and Institute Identified for the Application, and the Expertise on the Review Panel

Given the diversity of social science and behavioral science research questions and methods, PIs need to take extra care to ensure that their application is assigned to the right Institute and reviewed by a research panel with appropriate expertise. Talking with program officers and doing research on review panels is particularly important for social and behavioral science researchers. These topics will be discussed in Chapters 2 and 9. Including a cover letter that identifies the appropriate Institute, suggests review panels, and clarifies the expertise needed to review your proposal is particularly important for social and behavioral science proposals.

SOME KEY OVERALL STRATEGIES FOR A SUCCESSFUL SOCIAL SCIENCE PROPOSAL

The remainder of this manual discusses strategies to write a successful R01 proposal in detail. This section offers some overall tips recommended by program officers, reviewers, and successful applicants to write a winning proposal:

REMEMBER:

Be sure to link every section back to your research question.

- **Your title is important.** The title is the first thing a reviewer will see and will also be used to assign your project to a review panel. The title needs to be concise, interesting, and clearly describe your project. Authors should continue to craft their title throughout proposal development and share it with others to see that it clearly expresses your research idea and has impact.

- **Choose a compelling, timely research topic.** Your research topic should not only meet a need expressed through NIH and the Institute's priorities, but it should address a need that is on the minds of reviewers or the general public. For social and behavioral science projects this is particularly important. Can you link your research to a policy initiative like the Affordable Care Act? Has the population been in the news like the increase in autism, the aging population, problems with people vaccinating their children, or violence like the Sandy Hook killings? While not all important research topics have this kind of media cachet, if your topic does address an issue of public interest, use it in your significance section.

- **Be sure to link every section back to your research question.** Your application should tell a story about why a particular problem needs further study and how your approach is the best way to research this topic. Each section should describe the aims in exactly the same way and show how each element contributes to that aim.

- **Proposals with the highest success rates speak about what's already known, what needs to be known, and how to get there.** An NIH proposal is not the place to claim that no one has ever done research on this topic before or explore completely new ground with methods seldom used. Completely new ideas are rarely funded at NIH. Proposals need to show innovation, but also demonstrate knowledge of the existing literature and build on existing research. Successful researchers go over their proposal to ensure that it answers four questions: 1) What do we know about this topic?, 2) What are the gaps in existing knowledge that need to be filled?, 3) How does this project and these methods fill that gap?, and 4) What is the impact of this project on public health or a particular health issue?

- **Writing needs to be clear, concise, and written for an educated audience that may not be familiar with your topic or methods**. One program officer explained that she tells applicants that they should *"pretend you are writing for your dentist – someone who is educated, but is not in your field."* Review panels always include clinicians, epidemiologists and others from different fields than the applicant. Any NIH proposal needs to explain each aspect of the proposal in language that can be understood by people who are not familiar with your methods or the problem you plan to address. Do not use jargon or get caught up with disciplinary arguments. Remember that you only have twelve pages to explain the significance, approaches, and analysis you plan to use. Using plain, concise language is particularly important given the page limits.

- **Follow the directions.** NIH staff expressed over and over that they are frustrated by otherwise good applications that are eliminated because they did not follow NIH's careful, explicit directions. Be sure that the fonts and margins fit the stated requirements. Follow all directions for page length, materials in various sections, appendices, support letters and so forth.

TIP:

One program officer explained that she tells applicants that they should "pretend you are writing for your dentist – someone who is educated, but is not in your field."

REMEMBER:

Allow enough time
to write and review
your proposal.

- **Assemble your team before you begin writing.** NIH looks carefully at who you include in your team and their track record of working together. The team should be assembled before writing your proposal and contribute to developing it. Preferably, you have worked with these people before. If you haven't, it may be important to do a small project with them before developing an R01 and publish the results.

- **Allow enough time to write and review your proposal.** Social and behavioral science proposals can often take six months to write given the need to find materials, complete pilot data, assemble the research team, identify host sites, and give time for adequate proposal review, and get institutional approvals. Experienced researchers and reviewers stress that it is important to find outside reviewers for your proposal and give them adequate time to review it. Team projects should include review from each member of the research team and their institution. Institutions also have their own review timelines. It is important to know these up front and factor them into your proposal development timeline.

- **Find a mentor to help you develop your idea.** Even the most experienced researchers can benefit from the advice of others in developing their proposals. More junior researchers are particularly encouraged to find a senior colleague with a track record of NIH funding to help them develop their proposal.

- **Be prepared to submit your idea more than once.** Given that only 15 percent of new R01 proposals are funded the first time, be prepared for the need to revise and resubmit your project. It is helpful to look at reviews as a critique of your work that provides insights into issues you may have missed. It is equally important to discuss reviews with your program officer and follow their advice in revision. ∎

Chapter 2:
Starting the Grant Application Process

Before you can begin filling in your National Institutes of Health (NIH) grant application, there are several steps you must take first. For instance, you have to define the research project idea for which you are seeking funding. This may seem rather obvious, but the process for doing so is anything but simple.

You will also have to determine whether your research project will even qualify for an NIH grant, and several factors influence that determination.

Then — before you write a single word of your application — you should map out a strategy for it, which can include the following:

- Determining if the R01 grant mechanism is right for you.
- Picking a research project that you feel passionate about, yet which meets NIH funding priorities at the same time.
- Choosing people with expertise and experience who can advise you as you work on your application.

Next, you will need to more clearly define your proposed research project. NIH has specific criteria for investigators it will support, and there are explicit concepts every grant application must include to be considered. For instance, how you formulate your project title and hypothesis can significantly influence your research's fundability.

Finally, you should develop a writing schedule to ensure that your grant application meets NIH's submission deadlines. There are several possible tactics that you may use to help you.

Now, let's walk through each of the steps.

QUALIFYING FOR AN NIH GRANT

You may have an amazing research idea that will shake the very roots of the scientific world, but if it does not meet the requirements set out by the NIH and its Institutes, Centers and Office (ICOs), your application will not get past the initial review.

First, every application topic must be consistent with the NIH mission statement:

"NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability."

The goals of the agency are:

- foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
- to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease;
- to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
- to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

In realizing these goals, the NIH provides leadership and direction to programs designed to improve the health of the Nation by conducting and supporting research:

- in the causes, diagnosis, prevention, and cure of human diseases;
- in the processes of human growth and development;
- in the biological effects of environmental contaminants;
- in the understanding of mental, addictive and physical disorders; and

- in directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health information specialists.

What this means:

The agency states that its goals include the following:

- Foster fundamental creative discoveries, innovative research strategies and their applications as a basis for ultimately protecting and improving health;
- Develop, maintain, and review scientific human and physical resources that will ensure the nation's capability to prevent disease;
- Expand the knowledge base in medical and associated sciences to enhance the nation's economic well-being and ensure a continued high return on the public investment in research; and
- Exemplify and promote the highest level of scientific integrity, public accountability and social responsibility in the conduct of science.

In order to understand the types of behavioral and social science projects funded by NIH, it is helpful to look at OBSSR's definition of the kinds of social and behavioral science it funds and its current priorities. OBSSR describes social and behavioral science research as divided into the categories of fundamental and applied research, which are often linked to each other. These categories are described as:

The core areas of behavioral and social sciences research are those that have a major and explicit focus on the understanding of behavioral or social processes, or on the use of these processes to predict or influence health outcomes or health risk factors. These core areas of research are divided into basic (or fundamental) research and applied research.

I. Basic or Fundamental Research

Basic research in the behavioral and social sciences is designed to further our understanding of fundamental mechanisms and patterns of behavioral and social functioning relevant to the Nation's health and well-being, and as they interact with each other, with biology and the environment.

As is the case with basic biomedical research, basic behavioral and social sciences research does not address disease outcomes per se. Rather, it is designed to elucidate knowledge about underlying mechanisms and processes, knowledge that is fundamental to improving the understanding, explanation, observation, prediction, prevention, and management of illnesses, as well as the promotion of optimal health and well being.

Basic behavioral and social research is divided into three categories: (A) research on behavioral and social processes; (B) biopsychosocial research (the study of the interactions of biological factors with behavioral or social variables and how they affect each other— i.e., the study of bi-directional multilevel relationships); and (C) research on methodology and measurement in the behavioral and social sciences.

II. Applied Research

Applied research in the behavioral and social sciences is designed to predict or influence health outcomes, risks, or protective factors. It is also concerned with the impact of illness or risk for illness on behavioral or social functioning.

Applied research is divided into five categories: (A) research on the identification and understanding of behavioral and social risk and protective factors associated with the onset and course of illness, and with health conditions; (B) research on the effects of illness or physical condition on behavioral and social functioning; (C) treatment outcomes research; (D) research on health promotion and disease prevention; and (E) research on institutional and organizational influences on health.

These categories of research can cover a wide range of projects. OBSSR gives detailed examples of what it means by each categories and types of research projects in that category on its website at http://obssr.od.nih.gov/about_obssr/ BSSR_CC/BSSR_definition/definition.aspx.

OBSSR's current strategic priorities emphasize collaboration across disciplines and bringing together biomedical and social science approaches. Two strategic priorities influence research direction for NIH overall:

"Next-generation" Measurement and Data:

The OBSSR will support and facilitate the next generation of behavioral and social sciences research by promoting methodologies that permit the collection and analysis of data to capture complex, real-world phenomena. These efforts include the development of applications for mobile devices and wireless technologies for data collection and intervention delivery and techniques for analysis and visualization of large and complicated datasets. Furthermore, the OBSSR will stimulate systems science approaches that integrate multiple levels of analysis - from cells to society - to understand better the ways in which individual, contextual, and organizational factors interact over time to determine health status.

Influence on Population Health:

The OBSSR will facilitate collaborative research across the full range of disciplines and stakeholders necessary to elucidate the complex determinants of health and health systems challenges. Such collaborations will yield new conceptual frameworks to promote life-course well-being, address health care disparities, and employ novel methods, measures, and technologies to speed the improvement of population and public health.

What this means:

NIH promotes social and behavioral science research that will either provide answers to fundamental theoretical issues or explain core issues related to disease, health, and health systems. It will as sponsor applied projects that develop and evaluate new tools to improve health or address an issue of public health. It especially promotes projects that involve interdisciplinary collaborations and link research "from bench to bedside" so that fundamental research in both biological and social sciences leads to improvements in health care and public health. This suggests that NIH would fund projects:

- to understand the experience of families of children with autism
- explore how social networks provide resources to people recovering from disease
- identify the ways that people who become disabled later in life understand their limitations and respond to efforts to improve their health
- understand the impact of fracking on cancer or other diseases
- explore how poverty impacts access to health care after the implementation of the Affordable Care Act
- understand how to ensure privacy if electronic records are available through cell phones, tablets or other wireless devices
- evaluate a tool to improve screening for diabetes

The agency is not likely to fund projects to:

- understand how lack of recreational facilities limits quality of life
- interventions to improve employment for people with disabilities without reference to their health
- projects to promote health education through cell phones similar to innovations that have been proven successful for many years.

Consequently, your initial step must be to review the above qualifying elements and compare them to your proposed research idea. If there is a good match, then you should move forward with your grant application.

If your proposed research does not meet NIH mission or other requirements, however, you should consider seeking a grant award from another source, such as the National Science Foundation (NSF). For example, NIH might fund research on the role of social networks in improving health. Whereas NSF- sponsored research in the nature of social networks, the role of social networks in employment, or the differences between networking through social media and other forms of social networks.

TIP:

Review NIH's qualifying elements and compare them to your proposed research idea to make sure they match up before you move forward with your grant application.

Institutes, Centers and Offices (ICOs) Also Weigh in

Next, you must consider that NIH is made up of 27 semiautonomous ICOs. And each of these has its own defined research focus.

The NIH's Center for Scientific Review (CSR) staff performs the initial review of your grant application before assigning it to one of its review panels called Study Sections, which are organized around specific scientific subject matter. Nonetheless, you can suggest that a specific Study Section review your application, even though the CSR has the final decision.

Of the 27 ICOs, the following accept R01 grant applications for investigator-initiated research proposals for social and behavioral science:

National Cancer Institute (NCI, www.cancer.gov) — Through basic and clinical biomedical research and training, the NCI conducts and supports research regarding cancer prevention and/or manageability, early-stage identification, innovative treatment development. Current research priorities in global health and prevention and early detection of cancer may provide the most opportunities for social and behavioral scientists. NCI also sponsors a provocative questions initiative that focuses on such topics as cancer prevention and risk; diagnosis, and prognosis; cancer therapy and outcomes; and clinical effectiveness.

National Eye Institute (NEI, www.nei.nih.gov) — NEI conducts and supports research that seeks to prevent and treat eye diseases and other vision disorders, including sight-saving treatments, visual impairment and blindness reduction, and quality-of-life improvements.

National Heart, Lung and Blood Institute (NHLBI, www.nhlbi.nih.gov) — NHLBI backs grants centered on treating diseases of the heart, blood vessels, lungs and blood; blood resources; and sleep disorders. NHLBI funds a number of projects related to preventing heart disease, high blood pressure, and other diseases under its auspices. Special initiatives on obesity may also be of interest to social and behavioral science researchers.

National Human Genome Research Institute (NHGRI, www.genome.gov) — Devoted to advancing health through genome research, the NHGRI supports research aimed at expanding understanding of human biology and improving human health.

National Institute on Aging (NIA, www.nia.nih.gov) — The NIA leads a national research program regarding the biomedical, social and behavioral aspects of the aging process; age-related disease and disability prevention; and a better quality of life for older Americans. It is a major funder of social and behavioral science research.

National Institute on Alcohol Abuse and Alcoholism
(NIAAA, www.niaaa.nih.gov) — NIAAA focuses on research to improve the treatment and prevention of alcoholism and alcohol-related problems. NIAAA is a major funder of social and behavioral science research. Its current priorities include:

- Preventing children and adolescents from drinking alcohol
- Offering effective intervention for alcohol abuse for all ages

National Institute of Allergy and Infectious Diseases
(NIAID, www.niaid.nih.gov) — NIAID's research centers on understanding, treating, and preventing infectious, immunologic, and allergic diseases.

National Institute of Arthritis and Musculoskeletal and Skin Diseases
(NIAMS, www.niams.nih.gov) — NIAMS supports research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases; as well as basic and clinical scientist training to carry out this research.

National Institute of Biomedical Imaging and Bioengineering
 (NIBIB, www.nibib.nih.gov) — NIBIB promotes fundamental discoveries, design, and development, and translation and assessment of technological capabilities in biomedical imaging and bioengineering, enabled by relevant areas of information science, physics, chemistry, mathematics, materials science and computer sciences.

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD, www.nichd.nih.gov) — The NICHD supports child-centered research regarding fertility, pregnancy, growth, development and medical rehabilitation. NICHD is also a major funder for research on intellectual and developmental disabilities for people of all ages. NICHD is a major funder of behavioral and social science research.

National Institute on Deafness and Other Communication Diseases
(NIDCD, www.nidcd.nih.gov) — The NIDCD conducts and supports biomedical research and research training on normal mechanisms as well as diseases and disorders of hearing, balance, smell, taste, voice, speech and language.

National Institute of Dental and Craniofacial Research
 (NIDCR, www.nidcr.nih.gov) — NIDCR leads national research to understand, treat, and prevent infectious and inherited craniofacial-oral-dental diseases and disorders.

National Institute of Diabetes and Digestive and Kidney Diseases
 (NIDDK, www2.niddk.nih.gov) — NIDDK conducts and supports basic and applied research regarding diabetes, endocrinology and metabolic diseases; digestive diseases and nutrition; and kidney, urologic and hematologic diseases. Research on prevention, health disparities and obesity may be particularly appropriate for social and behavioral scientists.

National Institute on Drug Abuse (NIDA, www.nida.nih.gov) — NIDA's funding efforts focus on research across several disciplines to improve drug abuse and addiction prevention, treatment and policy. NIDA is a major funder of social and behavioral science research.

National Institute of Environmental Health Sciences
 (NIEHS, www.niehs.nih.gov) — NIEHS seeks to define how environmental exposures, genetic susceptibility and age interact to affect an individual's health.

National Institute of General Medical Sciences
(NIGMS, www.nigms.nih.gov) — The NIGMS supports basic biomedical research that is not targeted to specific diseases. NIGMS funds studies on genes, proteins and cells, as well as on fundamental processes like communication with and between cells, how our bodies use energy and how we respond to medicines. NIGMS also supports research training programs for biomedical scientists and has special programs to encourage underrepresented minorities to pursue biomedical research careers.

National Institute of Mental Health (NIMH, www.nimh.nih.gov) — NIMH is dedicated to understanding, treating and preventing mental illnesses through basic research on mental illness, and through clinical, epidemiological and services research. In addition to mental illness, NIMH sponsors research on intellectual disabilities like ADHD/ADD and autism. NIMH is the largest funder of behavioral and social science at NIH. Its current priorities are:

- Promote discovery in the brain and behavioral sciences to encourage research on the sources of mental disorders
- Map mental illness trajectories to determine intervention methods
- Develop new and improved interventions that include the diverse needs and circumstances of people with mental illnesses
- Strengthen the public health impact of NIMH-supported research

National Institute on Minority Health and Health Disparities (NIMHD, www.nimhd.nih.gov) – NIMHD mission is to lead scientific research to improve minority health and eliminate health disparities by evaluating all minority health and health disparities research and activities of the NIH while supporting research in minority health and health disparities. While NIMHD is a small Institute, it is a large supporter of social and behavioral science research.

National Institute of Neurological Disorders and Stroke (NINDS, www. ninds.nih.gov) — NINDS's mission is to support and conduct research, both basic and clinical, on the normal and diseased nervous system, foster investigators' training in the basic and clinical neurosciences, and seek better understanding, diagnosis, treatment and prevention of neurological disorders.

National Institute on Nursing Research (NINR, www.ninr.nih.gov) — NINR awards grants for clinical and basic research to establish a scientific basis for individual patient care, including patient management during illness and recovery; risk reduction for disease and disability; promoting healthy lifestyles and quality of life for those with chronic illness; and caring for those at the end of life. This research may also include families within a community context, and may focus

on the special needs of at-risk and underserved populations, emphasizing health disparities. Social and behavioral science research related to nursing is often funded through this Institute.

National Library of Medicine (NLM, www.nlm.nih.gov) — NLM conducts and supports research in biomedical communications and provides grant for training, medical library resources, and biomedical informatics and communications research.

National Center for Complementary and Alternative Medicine (NCCAM, www.nccam.nih.gov) — The NCCAM explores complementary and alternative medicine (CAM) practices in the context of rigorous science and trains CAM researchers. Even though this Institute is small, it funds a significant number of social and behavioral science projects.

Now, let's look at how your particular research idea might fit into one of these ICO's coverage areas.

For example, if your proposal focused on obesity, you might find support from several different institutes like NHLBI, NIDDK, NICHD, or NIMHD. However, a project looking at the role of obesity in heart disease would be most welcomed at NHLBI while one focusing on diabetes prevention would fit better at NIDDK.

Alternatively, if your research focused on the causes of violence among the mentally ill, it would fit best at NIMH.

One tactic for selecting which ICO(s) might be the best fit is to contact specific institutional program officers — frequently called POs — to assess their level of enthusiasm for your research and how it might fit into any initiatives that group might be considering. If you feel your proposal could fall under more than one ICO, you can contact POs at each Institute for direction.

STRATEGY:

You can specifically request in your cover letter that your application be forwarded to a particular ICO for consideration. And you can contact institutional program officers at each ICO for direction.

How do you find a relevant PO for your proposal? Once you have selected the ICO(s) that best fit with your proposed research, go to that group's Web site. Once there, you can review the staff directory to locate the appropriate PO. For example, on the NAIAD site you can click on "Grants" under "Funding," and there you will find a link for "Grant Application." Once there, you can click on the "Contact Staff for Help" link. Contact the program officer by email with a brief outline of your project. If he or she feels that another PO with a different portfolio in this Institute or another Institute might be a better fit.

When you speak with the PO you have identified, you can request details regarding possible topics for investigator-initiated research, such as the following:

- new scientific directions and opportunities, including published concepts (for example, NIAID posts its Concepts: Potential Opportunities on its Web site, www.niaid.nih.gov)
- unpublished high-priority topics

It is best to initially approach a PO via email with a very brief but clear outline of your project. The outline should be a brief, one-page or less lay explanation of your research. You should not approach a program officer until you have a clear idea for your research and have done your homework on what else has been funded that is similar. Program Officers have limited time and many projects to discuss so it is important to be prepared for a conversation with them. They do not appreciate fishing expeditions or researchers that ask them what they are interested in funding at the moment. You should have looked at other projects they fund and any priority research areas before contacting them. For example, NICHD suggests the following outline for your proposal summary:

TIP:

It is best to initially approach a PO via email with a very brief but clear outline of your project. The outline should be a brief, one-page or less lay explanation of your research.

- Primary research question(s). Include an explanation of why the research question(s) are significant.
- Specific hypotheses
  - o Specify dependent and independent variables and expected relationships
  - o Discuss mechanisms through which independent variables affect dependent variables
- Methodology
  - o Explain why the methodology is appropriate to address the hypotheses
  - o Describe data collection methods (if applicable)
- Estimated budget (direct costs).
- Time line[2]

Unless you have an opportunity to meet with a PO at a professional meeting or other venue, conversations with program officers generally take place by phone and are scheduled in advance via email. These meetings should be short and to the point given the time constraints faced by program officers.

This meeting is also a great time to make a friend of your PO, making sure to consider any offered advice seriously. Developing a relationship with a program officer is an important step in your ability to get funding at NIH. The PO can provide guidance on funding priorities and resources as you develop your research proposal. Some will give you feedback on your research ideas. Depending on the Institute, the PO may have an active role in suggesting which projects that are scored at a level to receive funding will be funded if only some of the projects can be funded due to budget constraints. If your project is turned down, they may be able to help you interpret reviews and clarify whether or not to resubmit. They may also be responsible for your grant after it is funded.

---

[2] From NICHD hand out Thinking of Applying to NICHD? Contact a Program Official. See also http://link.springer.com/article/10 .1007%2Fs11113-013-9306-5 Regina Bures, Rebecca Clark, Rosalind King & Susan Newcomer (2014). Funding Strategies for Population Researchers: Perspectives from the National Institutes of Health. Population Research and Policy Review, February 2014 (33)1: 1-11.

Program officers can also help you navigate the funding process and dispel myths about what gets funded, program priorities, budget cuts and other issues. POs prefer to know if there are rumors about changing priorities or new initiatives so that they can address them head on. While it is not a good idea to ask about things tangential to the research process, POs can serve as an important resource throughout the proposal development and review process.

Your Institution Must Qualify for NIH Support as Well

In addition to your research qualifying for NIH support, your host institution must also qualify.

In fact, NIH actually awards most grant types — including R01 grants — to the institution rather than to the individual applying for the grant. Universities, small and large businesses, and foreign institutions are among those that qualify for R01 grants.

On the other hand, NIH limits the eligibility for other types of grants. For instance, foreign institutions may not apply for small business awards such as an SBIR grant. Similarly, most federal organizations may receive NIH grants, but those in the Public Health Services may get NIH funds only under exceptional circumstances.

Keep in mind that although NIH grants primarily go to domestic institutions, you do not need U.S. citizenship or affiliation to become a principal investigator for most grant types, including an R01. You, however, must have U.S. citizenship for a small business award, and you must be a U.S. citizen or a permanent resident — that is, have an Alien Registration Card — for fellowships, career development awards (with one minor exception) and training grants.

NIH also outlines the following requirements for foreign principal investigators working on NIH-funded grants:

REMEMBER:

NIH actually awards most grant types — including R01 grants — to the institution rather than to the individual applying for the grant.

- If you are not a U.S. citizen but working at a U.S. institution, you must remain there long enough to finish your project.
  - o If you do not have a permanent visa, state in your application that your visa will allow you to remain in the United States long enough to be productive on the project.
  - o Your institution must ensure that you have an appropriate visa.
- Persons from countries listed as State Sponsors of Terrorism cannot work with any agent covered by the USA Patriot Act.

Additionally, when a foreign institution submits an application, NIH requires additional steps to register for electronic application.

Qualifying for an R01 NIH Grant

NIH supports scientists at various stages in their careers, from pre-doctoral fellowships to investigators with extensive experience who run large research centers. Nonetheless, the agency — as well as some of its ICOs — does have minimal eligibility requirements for most research grants, including the R01.

Here are NIH's criteria if you are seeking an independent research grant, such as an R01:

- Hold an advanced degree appropriate to the research (in most fields, you likely would need a Ph.D. or M.D.)
- Within your institution, hold a position or rank that allows you to apply for such grants (often assistant professor or higher).
- Have a publication or patent record or a history of high-level research supervision in the field in which you are applying.
- Work in a research institution that has the resources — meaning library and computing resources, a teaching schedule that allows time for research, access to communities or medical facilities to do your research, centers with

supportive colleagues or additional research resources like GIS or statistical data sets, and the willingness to provide course releases, research assistants, or students for service learning courses — you will need.

You must show the NIH peer reviewers that you can handle leading a major research project. That means your grant application must clearly demonstrate your expert qualifications, your institute's commitment to you and your project, and the institutional resources and research partners you will have by the time NIH or one of its ICOs makes the award.

If you find that you do not meet NIH's R01 qualifications, the agency offers other funding mechanisms that might be more appropriate and prepare you substantially for your first R01 opportunity. These can take the form of a Pathway to Independence Award or New Innovator Award.

MAP OUT YOUR PLAN

Understand that from the start that the grant application process takes a good deal of time. Generally, experts recommend that you should plan to spend roughly two months or longer preparing your R01 application. And if your research will require human or animal subjects, the preparation time could increase as much as six months.

Even if your application flies through the review process on the first try and is approved for funding, you likely will not see a penny of the award for another six to 18 months.

Reviewers, however, may not approve an application on its first pass through the process. And even with approval, you may not receive funding for your proposal, depending on the amount of money available for approved applications.

And because NIH funds approximately 17 percent of the R01 and R01 equivalent applications it receives, most applicants must revise and resubmit their proposals. This means your award might not be forthcoming for as long as 28 months from the time you initially apply until you potentially receive funding based on your resubmission.

Therefore, having a game plan for your application is a must.

Nail Down Your Strategy

The average NIH grant lasts three to five years. Consequently, one grant will not fund your life's work as a researcher.

As a result, you should look further down the road in your career. One option is to plan your research goals for a longer period — for instance, the next 10 years. Then you can divide your goals into segments that you can accomplish in three to five years.

TIP:

Experts recommend that you plan to spend roughly two months or longer preparing your R01 application.

Suppose, for example, you choose to study the role of resource networks in successful outcomes for people with autism spectrum disorders. This is a broad topic, so you break your research into three grant topics, each covering three years:

1. a foundational study exploring the nature of family, organizational, and other networks that either lead to successful transition from childhood education to adult programs or do not

2. a translational research project using the results of your first study to create tools to identify networks for transitioning youth with autism spectrum disorders and develop interventions to enhance network creation and effectiveness

3. an implementation study of an intervention using the tools and interventions developed in stage 3

This particular approach has three advantages:

•   It keeps your research projects small and manageable. When applying for a grant, you should propose an amount of work that you can do within the time and resources you request. New investigators, in particular, frequently propose too much in one application, and reviewers may reject their proposals merely because there is an unreasonable amount of work involved.

•   It forces you to consider your research in terms of maintaining your career, which helps you to avoid the common pitfall of failing to get a renewal for your project.

•   This type of big-picture planning helps to keep you focused on your main idea, as well as how you will pursue it for several years of funding.

Make Sure the R01 Is the Right Mechanism for You

As part of your grant application strategy, you must determine whether the R01 grant mechanism is right for your proposed area of research. As a first step, you should speak with your identified PO and with experienced investigators in your institution or other senior colleagues for their guidance. Another resource likely will be your institution's sponsored research office.

NIH offers hundreds of specialized award types with varying characteristics, so if this is your first application, you should seek guidance in choosing your grant mechanism. In addition, there are other issues that only add to the complexity:

- Not all ICOs participate in all the grant activity codes. For instance, most ICOs use R01s, but there are several — such as the National Cancer Institute — that do not use R03s (for small research programs).
- Different ICOs or initiatives may have different requirements even for the same activity code. For example, AIDS-related R01 applications have different deadlines than other R01s.
- ICOs might use a certain grant type for only certain areas of science. For instance, if your research involves marketing a tool to transfer electronic medical records between institutions, you might consider an SBIR mechanism, which assists researchers in commercializing innovative technologies, rather than an R01.

One strategy is to speak with a relevant PO at NIH who may help you focus down on the grant mechanism that is right for your proposed research.

Specifically when requesting an R01 award, you should remember that these provide three to five years of support to researchers who have preliminary data. If you lack this, consider an exploratory/developmental research grant (R21) or a small grant (R03) that will fund such efforts. The data you thereby obtain will then support a later R01 application.

STRATEGY:

Speak with a relevant NIH PO who may help you focus down on the grant mechanism that is right for your proposed research.

CHOOSE YOUR PROJECT

There are seven points you should consider when choosing your R01 research area:

1. **Pick a research topic that will allow you to make a large impact on a focused area.** Your peer reviewers will examine your grant application to determine how your research will advance the scientific field. In fact, this, along with your project's feasibility, likely will be the determining factors regarding your research's fundability. The more focused your project, the less likely it will overlap with another application. Consider the following questions when selecting your topic:

   - Can the research make a difference? For instance, will it open a new area of discovery or develop a new approach to a significant problem?
   - Will reviewers consider your research area to have the same priority that you do? Get an unbiased opinion from a mentor or other trusted colleague.
   - How will your idea stack up against NIH review criteria? We will examine these criteria in later sections of this manual.

2. **Define the current gaps and opportunities in your field.** Carve out your own research niche. Avoid crowded areas because making a difference will be more difficult when you have more competitors. At the same time, find an interesting challenge that you likely will be able to solve. Read the scientific literature so you understand the current state of the problem(s) you want to address and what research to avoid because it has already been accomplished. Also, brainstorm ideas with colleagues.

3. **Be an expert.** Perhaps obviously, you should choose a research topic within your area of expertise. Although you can recruit collaborators to fill experience gaps, you should have first-hand knowledge of the science and most of the methods related to your grant application. Reviewers expect you to be the expert in your proposed investigational area, and this must be supported in your application. Assess your strengths and how they match the requirements of potential projects.

4. **Examine potential research areas at NIH.** The R01 grant mechanism is for investigator-initiated research, which allows you to select the topic. But you should also review the priorities at the various ICOs to determine if your proposal fits among their stated internally or forecasted research needs.

5. **Make sure your project is doable.** Consider writing a single sentence that demonstrates how your project is well-focused, makes an impact and has a testable hypothesis or clear, manageable research question. By limiting yourself to this format, this will help you determine if you can truly accomplish your research goals within your award period and using the level of resources that you might request. Also make sure that your science relates to the cause, diagnosis, prevention or cure of human disease — which ties it squarely to the NIH mission statement.

6. **Get advice on your project's merits.** Obtain the NIH PO's opinion regarding your research idea. Speak with experts at your institution and other colleagues to get their perspective concerning your proposed research's impact. Based on this input, rate the impact of your topic. If it scores poorly, refine your idea or find another topic.

7. **Look at your proposed topic through a reviewer's eyes.** Find the Study Sections that likely would review your area of science, and identify three or more members who would likely serve as your reviewers. Although these may not turn out to be your actual reviewers, they likely will have similar expertise to those who are. Review their published writings, and keep them in mind as you construct and review your application. This will give you an idea of the how they might assess your proposal.

Once you have worked through all seven of these points, you should be able to distill your research topic into a sufficiently focused idea that will allow you to develop your grant application more readily.

TIP:

Write a single sentence that demonstrates how your project is well-focused, makes an impact and has a testable hypothesis.

DEFINE YOUR PROJECT

When determining what your research project will entail, follow these steps to help you stay on track:

- Create a solid, testable hypothesis or clear, manageable research question
- Write a provisional title
- Decide when to apply

Creating Your Hypothesis or Research Question

Most successful grant applications start with a focused, testable hypothesis, or clear research question that can be studied in the space of a 3-5 year study. Your research design should be able to prove — or disprove — your hypothesis or shed light on your research question. In fact, your application should ask questions that test your hypothesis rather than indicate you are searching for a problem or simply collecting information.

Think of your hypothesis or research questions as the glue that holds your application together. The results of your research will ultimately determine whether your hypothesis or research question is good science.

Also keep in mind that you should never force a hypothesis on research that is not truly hypothesis-driven. A statement such as, *"research on the role of social networks in the transition to adulthood in the general population suggests that the same factors would be important for transition age adults with autism"* suggests a broad topic which requires general exploration before developing specific hypothesis. Some types of social sciences use more general research questions in their research than specific hypothesis. The trick is to develop a research question that is framed in a way that is similar to a hypothesis and is specific. For example:

1. *How do social networks and resources through organizations such as schools, disability sports leagues, social or service organizations for people with disabilities and their families, or more general supportive institutions like churches help or hinder transition age youth with autism spectrum disorders (ASD) in their transition to adulthood?*

    a. *Are the individual and organizational networks of youth with autism and their families different from those of other transition age youth? In what ways?*

    b. *What types of institutional and organizational networks are beneficial to ASD youth and their families? Why and in what specific ways?*

    c. *What types of institutional and organizational networks create barriers to ASD youth's successful transition? Why and in what specific ways?*

Note that that these questions are specific enough to show a clear target for the research project. For example "*What are the networks of ASD youth and their families?*" is too vague for a successful application. Projects that use research questions imply that the field does not have enough information for hypothesis driven research. For example, if we do not know the nature of the networks of ASD youth and their families, it would be premature to propose a hypothesis like, *"The families of ASD youth who do not successfully transition to adult services will have smaller social networks and fewer institutional supports."*

In addition, you should explicitly state your specific, falsifiable hypothesis. Regardless of whether you have a general, overarching one that covers the entire proposal or a specific one for each research aim, there should be a hypothesis or clear research question in your application. One program officer suggested the following as examples of good and bad hypothesis for social and behavioral science projects:

TIP:

Use research questions instead of hypothesis for foundational studies. Think of your hypothesis as the glue that holds your application together, and never force a hypothesis on experiments that are not truly hypothesis-driven.

A bad hypothesis:

An excessive work ethic causes heart disease, cancer, and anxiety sometimes.

What's wrong?

- Independent variable (excessive work ethic) is hard to define and relative to the beliefs, norms and values which differ among groups and individuals. (Who thinks it's excessive? How do operationalize this relative to differing perspectives?)
- Dependent variables are broad and ill-defined. (What kind of heart disease? What kind of cancer? What level of anxiety?)
- Too many dependent variables in one hypothesis. How might one ever demonstrate the truth of this hypothesis?
- The worst part of this hypothesis is the word "causal." It's extremely difficult to prove causation especially for three ill specified dependent variables.
- In research one is supposed to disprove the null hypothesis, suggesting that proposed hypothesis has not been disproved and so there is a chance for its validity.
- It would be impossible to reject the null hypothesis because of the term "sometimes." What does that mean? It's impossible to disprove the statement that causation doesn't happen sometimes because there is no way that we can observe all of the occasions that might happen. It's impossible to prove or disprove the hypothesis.

In writing your hypothesis it is better to be specific, measurable, and stay away from causality. An example of a good hypothesis:

1. Working 60 hours per week or more over the period of a year is significantly associated with increased prevalence of cardiac arrhythmias in adults.

2. Working 60 hours per week or more over the period of a year is significantly associated with an increased risk of several cancers in adults.

3. Working 60 hours per week or more over the period of a year is significantly associated with an increased prevalence of clinically measured levels of anxiety in adults.

The term risk is used instead of prevalence because the onset of cancer may occur a rather long period of time after exposure to a risk factor.

Research that tests a hypothesis is likely to give meaningful results, regardless of whether the data support or refute the hypothesis. NIH generally prefers grant proposals that have an impact on future research, and a testable, significant hypothesis can provide that impact.

Write a Provisional Title

The next step is writing an initial or working title to further focus your research idea and guide preparation.

Direct from NIH: The NIH Application Guide states:

Descriptive Title of Applicant's Project

Enter a brief descriptive title of the project. This field is required (Part I: Instructions for Preparing and Submitting an Application I-47PHS SF424 (R&R) Adobe Forms Version C Application Guide).

A "new" application must have a different title from any other PHS project submitted for the same application due date with the same PD/PI. A "resubmission" or "renewal" application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title.

A "revision" application must have the same title as the currently funded grant.

NIH and other PHS agencies limit title character length to 200 characters, including the spaces between words and punctuation.

What this means:

You will finalize your title after completing your application. All reviewers will read it, so it must be informative. It may even color perception of your entire submission. At the same time, the NIH grant application limits your title to 200 characters, including letters, numbers, spaces and any punctuation.

The title is your first chance to win over reviewers with an innovative, creative idea that they will want to champion for funding. Consequently, a title that stands out from others and virtually compels reviewers to read your application gives you one more advantage.

By the way, keep in mind that — far from the niches of science — companies struggle to condense powerful advertising messages into terse phrases. For example, "Coke is it" or "A diamond is forever." Even newspaper headline writers grapple with this challenge.

One senior scientist and peer reviewer at NIH recommends: *"Spend a lot of time writing the title – that is the key thing for the project"*.

Therefore, your title is a significant piece of information that must be a unique, relevant and intriguing description of your research plan that conveys the following:

- What you will do
- How you will do it
- What the results will be

REMEMBER:

NIH limits your title to 200 characters, including letters, numbers, spaces and any punctuation.

Because NIH wants to fund work that can seriously impact society and advance science, you should point to the outcome of your research in the title.

Keeping all this in mind, here are 13 tips for creating successful titles:

1. **Be original and relevant.** Make sure your title differs from those of already submitted applications or from funded research. NIH wants fresh, innovative projects. You can review databases of existing applications and awards at www.projectreporter.nih.gov and contact the appropriate NIH scientific review officer to ensure that your title is not redundant or closely similar to another.

2. **Be accurate and use agency-friendly keywords** that help officials direct your proposal to the appropriate study section. For example, using "epidemiology of" in the title will help the reviewer route the application to an epidemiology study section, such as the Neurological, Aging and Musculoskeletal Epidemiology (NAME) Study Section. If you are looking the social characteristics of a mental health condition, you may instead want to say the "Behavioral characteristics of X condition" to get to the right study section.

3. **Find out which themes are mission-relevant, priority areas for research, or emerging as future priorities**. Decision-makers at NIH seek advice from many sources when setting research priorities, including the scientific community at-large, federal advisory councils, individual researchers, professional societies, patient organizations, and voluntary health associations. Areas which continue to receive attention include cancer, HIV/AIDS, pediatric and adult obesity, and aging related topics. Recent emphasis across the NIH on systems approaches to health issues influences proposals at many institutes and centers. Since each individual IC sets its own priorities based on the input it receives, it is best to check each one for their most current areas of emphasis.

4. **Use results-driven words** instead of those that describe your process. For example, from funded R01 applications:

- DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES?
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8468334)
- EXPLORING EXPERIENCES OF DISCLOSING HIV-POSITIVE STATUS WHILE IN PRISON
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8465343)
- A MOBILE PERSONAL HEALTH RECORD FOR BEHAVIORAL HEALTH HOMES
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8495589)
- STRESS-INDUCED MARIJUANA SELF-ADMINISTRATION: ROLE OF SEX AND OXYTOCIN
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8561004)
- UNDERSTANDING HOW PERSONAL NETWORKS CHANGE
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8506360)
- FAMILY OUTCOMES IN AUTISM SPECTRUM DISORDERS
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8524248)

You will notice that all of these titles conform to the previous descriptive title character limit of 81 characters. The new 200 character limit will be reflected in R01 submissions beginning in October 2014.

5. **Be authoritative.** That means that you should let reviewers know that you know what you are talking about. For instance, if your research focuses on social networks for transitioning youth with ASD an authoritative

title might be "The Role of social networks and institutional supports in successful transitions for youth with Autism Spectrum Disorders." This title suggests that this is an important topic rather than an exploration of how social networks might influence transitions. A less effective title might be "Exploring the potential for social capital to influence outcomes for ASD youth and their families." This second title suggests that this is an exploratory study which may be better as a smaller grant. It also is less authoritative because it speaks of potential rather than stating that there is a role of social networks. It also uses more jargon and the less understood term "social capital" rather than the specific "social networks and institutional supports."

6. **Keep NIH criteria in mind**, including significance, innovation, investigators, approach and environment. For instance, "A Mobile Personal Health Record For Behavioral Health Homes" shows significance by addressing electronic records and behavioral health homes, both currently high on the policy agenda. A mobile personal health record would be an innovation. This title encourages the reader to look more closely at the other aspects of the project.

7. **Use plain language.** Consider the simple, direct and economical use of the words that make up this successful grant proposal title, "Public Health Preparedness and Response for Bioterrorism". Alternatively, a wordy, awkward and dramatic way of saying the same thing might be "Will Public Health Authorities Be Ready When and If the Horrors of Bioterrorism Unfold in Their Cities?"

8. **Follow the rules.** As stated earlier, the NIH application limits title length to 200 characters. If yours is longer, it will be cut off at the 201st character, which could strip away the meaning and impact carried by the deleted words.

Use active, forward-thinking verbs, such as "defining," "improving" or "development," that tell readers your project points to results. For example, consider the following from awarded R01 applications:

- SUBSTANCE USE IN RESERVISTS SOCIAL AND ENVIRONMENTAL INFLUENCES
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8505856)
- A RANDOMIZED CLINICAL TRIAL OF CULTURALLY TAILORED MI
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8438022)
- THE AUTISM IMPACT MEASURE: A NEW TOOL FOR TREATMENT OUTCOME MEASUREMENT
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8575724)
- THE TIMES ARE CHANGING: A QUALITATIVE STUDY OF OLDER AND YOUNGER MARIJUANA USERS
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8458476)
- DISPARITIES IN CANCER SCREENING: THE ROLE OF MEDICAID POLICY
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8562222)
- COMMUNICATION AND ECONOMIC OUTCOMES FOR CANCER SURVIVORS
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8501827)
- NEIGHBORHOOD FACTORS AND CHILD MALTREATMENT: A MIXED METHOD STUDY
  (See: http://projectreporter.nih.gov/project_info_description.cfm?aid=8558865)

REMEMBER:

NIH uses your title and abstract to report your research dollars to Congress.

9. **View your title as a work in progress.** Your final title may differ from your initial one because a proposal's specifics typically change during the writing process. Finalize your provisional title when you have completed the application.

10. **Get input from peer scientists and individuals outside your field,** preferably an English professor or an editor for proofreading and language use. Colleagues with grant-writing experience can be especially helpful.

11. **If you are resubmitting, keep your proposal's original title** so that agency officials easily recognize it and look for the changes that you have made.

12. **Proofread your title** before you hit the "send" button. Do not rely on your spell-checking program. Instead, use a dictionary because terminology must be spelled correctly. A seemingly insignificant error could destroy your chances of winning funding.

Finally, remember that NIH uses your title — as well as your abstract — to assign your application to a study section and Institute for review. The agency also uses it to report your research dollars to Congress. So your title plays a vital role not only in the review process, but also throughout the life of your research and grant.

Deciding When to Apply

NIH has three annual deadlines for submitting applications for new R01 grants: Feb. 5, June 5 and Oct. 5. For renewal R01 applications, these dates shift to March 5, July 5 and Nov. 5. And if you are submitting an AIDS or AIDS-related R01 application, there are different deadlines: Jan. 7, May 7 and Sept. 7. At the same time, if your proposal is a response to an ICO's special request for a specific research topic, the ICO can choose a special deadline at its discretion, which you can find on the ICO's Web site.

R01 Type	Grant Cycle 1 Deadline	Grant Cycle 2 Deadline	Grant Cycle 3 Deadline
New Grant Application	Feb. 5	June 5	Oct. 5
Renewal Grant Application	March 5	July 5	Nov. 5
AIDS/AIDS-related Grant Application	May 7	Sept 7	Jan 7

Tactically, many researchers wonder if they should target a particular deadline because the competition might not be as great at that time of year.

Officially, NIH maintains that you should submit your grant application based upon the quality of the science rather than perceived differences in funding success rates during the various grant cycles. An outstanding proposal will always attract strong consideration regardless of what time of year you submit it.

Therefore, you should submit your application as soon as your ideas are fully developed, capable of being clearly presented and well supported by convincing preliminary data.

That said, if your grant proposal scores near the percentile cutoff point for funding, timing can make a difference. But this situation does not represent a substantially better success rate.

Note: The deadlines above are accurate as of May 2015. Changes may occur, however, and you should reconfirm your various deadlines for the grant cycles relevant to your application.

CREATE A WRITING SCHEDULE

Now that you have developed a provisional title and hypothesis, you can establish a writing schedule to ensure that your application is ready to submit before one of the grant cycle deadlines.

There is a great deal of information to accumulate, digest and then integrate into your application, and this will take time. The last thing you want is to submit a grant proposal that is incomplete, sloppy or shortsighted because you ran out of time. As part of your writing schedule, consider other responsibilities that you currently have, such as teaching, lab duties, personal obligations, etc.

STRATEGY:

Allow at least two months for planning and writing your grant application, at least one month to get feedback on it, and then two weeks for final reviewing and proofreading before submitting it.

NIH suggests allowing at least two months for planning and writing your grant application, at least one month to get feedback on it, and then two weeks for reviewing and proofreading before submitting it. Of course, the more complex your proposed research, the longer each stage of the process will take. Some experts even caution that preparing and writing your application can take as long as six months.

Consequently, you should set up a timetable for getting each section of the application completed and ready for review. For example:

Task	Due Date
Research field of interest to narrow research topic to manageable subject for application	
Review NIH Institutes and Centers for potential matching research focus	
Formulate hypothesis or research questions	
Create provisional title for grant proposal	
Submit hypothesis/research questions and title to colleagues for review and feedback	
Prepare Significance statement for Research Strategy section	
Prepare Innovation statement for Research Strategy section	
Outline Specific Aims section	
Etc.	

Once you have outlined your writing schedule, your last few tasks should involve assembling your application materials, having the packet reviewed by trusted colleagues (including a proofreader as well as those familiar with the science) and final submission before the deadline.

As you go through each task, do not attempt to make each section perfect on your first pass. Think of this stage as a work in progress. Once you have all the application sections completed in this rough-draft format, you can review the entire package as a whole, editing and rewriting to make sure that the sections flow more coherently. Then submit it in final form.

CONCLUSION

Once you have worked through the planning stages to clearly define your research project, choose your team, formulate your title and hypothesis, and develop your writing schedule, you will have laid the groundwork for writing a potentially successful R01 grant application. Moving forward, you will know your deadline to ensure your application arrives at NIH on time, as well as all the steps that must occur in the interim.

The more time and effort you put into your planning process, the more effective it will be and the more smoothly your proposal writing will be. Every grant application requires a great deal of information, work and time, and planning ahead only helps you to stay focus on your goals. ∎

Chapter 3:
Outlining Your Project and Individual Qualifications

There are specific sections of the National Institutes of Health's (NIH's) R01 grant application that allow you to outline your research topic and direction.

As you approach these areas, think of yourself as a storyteller. You are trying to get the reviewers emotionally involved to the point that they champion your proposal. All good stories have a resolution. Yours will be how your research will advance the scientific field and enable future investigations.

Your story begins with a Project Summary/Abstract, which is a brief yet detailed account of your proposed research. This section is important because initial NIH reviewers will use it to determine the study section that reviews your application. In addition, the Project Summary is the only section of your proposal that every reviewer reads. Most of them will scan the rest of your application, but they all read your Abstract in its entirety.

This chapter tells you what to include and what to leave out of your Project Summary. It also details NIH guidelines pertaining to Abstracts — such as the maximum number of pages — and gives you examples that illustrate what NIH wants to see.

We also examine the Biographical Sketch section, which is more than a simple biography of the principal investigator (PI). There are ways you can creatively use this area to increase your chances of successfully obtaining funding.

The Biographical Sketch section must include a personal statement, an account of the PI's positions and honors, a list of peer-reviewed publications or manuscripts in press, research support, and the newly required Section C, "Contribution to Science". This chapter describes each of these elements and how to effectively include them in your Biographical Sketch.

In addition, we explore the requirements for proposals with multiple PIs. You must provide a rationale for using this approach and a description of your plans for making it work. This chapter includes examples of appropriate documentation for applications with multiple PIs.

The chapter also explains how letters of support can help both new and established investigators applying for an R01 grant. It offers suggestions for the type of individual to provide a letter of support, clarifies why you should write the first draft of the letter for these individuals, and includes tips for crafting effective support letters.

FORMULATING YOUR PROJECT SUMMARY/ABSTRACT

Direct from NIH: The NIH Application Guide states:

Project Summary

The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information.

The **Project Summary** is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the **mission of the agency**). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct. This section must be no longer than 30 lines of text, and follow the required font and margin specifications. An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission. This would require a corrective action before the application will be accepted.

As noted above, do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the Project Description will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT, available at http://report.nih.gov) and will become public information.

The attachment must be in PDF format. (See Section 2.6 for additional information on preparing attachments.)

What this means:

NIH states that your Project Summary/Abstract should be "a succinct and accurate description of the proposed work when separated from the application." Further, "it should be a self-contained description of the project and should contain a statement of objectives and methods to be employed." It should also outline your application's broader, long-term goals and specific aims, as well as reference how your proposed research relates to human health, NIH says.

The agency also indicates that your intended audience for this section includes those "working in the same or related fields and insofar as possible [this section] should be understandable to a scientifically or technically literate lay reader." You can expect all of the peer reviewers to read this portion of your grant application.

At the same time, NIH warns that you should not include any proprietary or confidential information or trade secrets in the Project Summary. If you proposal receives funding, the summary becomes part of the public record.

Format Note: The Project Summary can be no longer than 30 lines of text. You must use the Arial, Helvetica, Palatino Linotype or Georgia font in black at 11 point size or larger. You may use a symbol font to insert Greek letters or special characters, but the font size requirement still applies. In addition, there can be no more than 15 characters — including characters and spaces — per inch. And there can be no more than six lines of text per inch, using at least half- inch margins on all sides of the 8½" x 11" page.

Keep in mind that initial reviewers in the Center for Scientific Research (CSR) likely will use the Project Summary/Abstract to assign your application to a particular Scientific Review Group (SRG) or study section, as well as to the peer reviewers who will examine it. Therefore, it should contain certain keywords so that SRG staff can readily assign your application and NIH computer systems can retrieve your grant properly. And SRG members who are not primary reviewers probably will rely heavily on your summary to understand your proposal during the group's general meeting to discuss application fundability.

Many grant-writing experts suggest that you write your Project Summary/ Abstract last as you construct your application materials. They maintain that this allows you to gain a more comprehensive understanding of your research proposal.

If you choose to write your Summary/Abstract early, you should consider it provisional and revisit it after you finish writing the rest of your application — especially the research plan — to make sure it is a true reflection of your proposal.

One rationale for writing a provisional Summary/Abstract early is to make sure that your proposal's main ideas are clear and concise in your mind. Once you have written the rest of your application materials, go through them with a highlighter (or the electronic equivalent), and mark all of the key terms that are important to understanding your research. Then revisit your provisional Abstract to make sure every keyword that you highlighted appears in a faithful context.

What to Include

Each of NIH's Institutes, Centers and Offices (ICOs) appears to have a slightly different idea regarding what you should include in this relatively brief description of your proposed research.

For example, the National Cancer Institute (NCI) indicates that your Project Summary should incorporate the following:

- A brief background of the project;
- Specific aims, objectives or hypotheses;
- Significance of the proposed research and relevance to public health;
- Unique features and innovation of the project;
- Methodology (action steps) to be used;
- Expected results; and
- Description of how your results will affect other research areas.

STRATEGY:

Many grant-writing experts suggest that you write your Project Summary/ Abstract last as you construct your application materials.

In addition, NCI indicates that the Abstract should succinctly describe every major aspect of the project except the budget. And it should have a distinct section that describes its relevance to public health.

NCI also offers the following suggestions regarding your Project Summary/ Abstract:

- Be complete, but brief.
- Use all of the space allowed (30 lines of text).
- Avoid describing past accomplishments and using the first person.
- Write the abstract last so that it reflects the entire proposal.
- Remember that NCI and NIH will use the abstract for purposes other than the review, such as to provide a brief grant description in annual reports, presentations and public dissemination.

The National Institute for Allergy and Infectious Diseases (NIAID), on the other hand, offers different —and quite specific — instructions along with a few similarities:

- In the first sentence, describe the significance of your research to your field and relevance to NIAID's mission: to better understand, treat, and prevent infectious, immunologic, and allergic diseases.
- Next, state your hypothesis and your research's innovative potential.
- Describe your Specific Aims and long-term objectives.
- Don't include graphs or images.

So be sure to examine your potential reviewing institutes' Project Summary requirements before you finalize this portion of your grant application.

Use Storytelling Tactics to Engage Reviewers

Most reviewers make up their minds regarding your proposal's merit as they read the first page of your application, according to principal investigators who have served in such roles. And they read the rest of your application looking to support their original impression.

Consequently, the quicker you grab their attention, the more likely you will engage them to support your proposal.

Your Project Summary/Abstract should present the opening chapter of your story, offering a short description of what the reader will find in the narrative. Therefore, the Summary should be a faithful, although condensed, replica of the narrative. NIH reviewers indicate that applicants often submit Abstracts that contain ideas found nowhere in the application's body, or Summaries that fail to include important ideas that do appear in the main sections.

REMEMBER:

The Summary should be a faithful, although condensed, replica of the narrative.

As stated earlier, reviewers use the Project Summary/Abstract to prepare themselves to intelligently read the application as a whole. Therefore, if the Abstract is an unfaithful map, they are like drivers heading into one state while holding a map of another.

A good place to begin your abstract is to get your reviewers' attention with the answers to four questions:

1. What is the problem or need that your proposal will address?
2. Why is it so important that it must be resolved? In other words, what is the significance?
3. Why are you the only person or group, or best-suited one, who can resolve the problem or need?
4. What is your proposed solution to address the problem?

Remember that you need to write a compelling story and your abstract should be a synopsis and introduction to that story. As one long term reviewer and successful applicant explained, you need to draw the reader's attention from the start. Many reviewers decide if they are interested in the application after reading the first page, and often the abstract or project summary is that first thing. As such, you need to be very careful about how you write this section.

Look to Project Summary/Abstract Examples

The follow examples are from actual funded NIH social and behavioral science applications

Example 1: From NCI sponsored project 1R01CA78980-01 DISPARITIES IN CANCER SCREENING: THE ROLE OF MEDICAID POLICY:

This study examines how existing and new policies that affect the generosity of state Medicaid programs impact breast and cervical cancer screening and related health outcomes among low-income women. There are substantial disparities in breast and cervical cancer diagnosis, treatment, and outcomes in the United States by race/ethnicity and socioeconomic and insurance status. Further, resources to improve access to and quality of care for underserved populations are limited. In recent years, the federal government granted many states increased flexibility to cover low-income adults through Medicaid waivers. Further expansions to Medicaid are anticipated under the Patient Protection and Affordable Care Act (ACA). Current variation in state Medicaid programs and anticipated changes under the ACA provide natural experiments for studying the effect of public insurance on screening for low-income women. We consider the effect of pre- and post-reform variation in eligibility between and within states, as well as the effect of physician payment and patient cost sharing on screening. Understanding how state Medicaid policies affect cancer screening will help guide strategies to reach under-screened populations and add to evidence regarding the costs and benefits of different policies. In addition, we study how variation in Medicaid generosity across states and over time is related to outcomes including cancer incidence

and stage at diagnosis, the single most important predictor of survival. The project brings together complementary secondary data from a number of sources. Nationally representative survey data from the Behavioral Risk Factor Surveillance System will be used to study the effects of Medicaid eligibility on breast and cervical cancer screening among low-income populations. Medicaid administrative claims and utilization data will allow us to consider the effects of changes in eligibility as well as physician payment and patient cost sharing on screening among Medicaid enrollees. Surveillance, Epidemiology, and End Results (SEER) cancer registry data will be used to estimate the effects of changes in Medicaid generosity on cancer incidence and stage at diagnosis. Our analytic approach employs a quasi experimental design to compare changes in outcomes among groups that would have been affected by changes in Medicaid policy (eligibility, payment rates, or cost sharing) to similar groups that were not subject to policy changes. In addition to considering the effect of policy changes on all low-income women, we will examine whether effects of expansions are larger among racial and ethnic minorities, reducing disparities. This is the first study to consider the effect of recent Medicaid policies regarding eligibility, physician payment, and cost sharing on breast and cervical cancer screening, which are the most important measures for the prevention of breast and cervical cancer morbidity and mortality. The results will provide timely evidence on how Medicaid policy affects women's preventive healthcare utilization and health outcomes.

Example 2: From NIDA sponsored project 1R01DA034072-01A1 SUBSTANCE USE IN RESERVISTS SOCIAL AND ENVIRONMENTAL INFLUENCES

Guided by a social ecological framework, this application will consider individual-level risk factors (e.g., depressive symptoms) and the influence of social (e.g., partner/peer behaviors) and environmental (e.g., life stress) factors on changes in substance use in US Reserve Soldiers. Substance abuse is the most common health problem among veterans 1 and substance use is linked to trauma, either in combat5 or at home.2 These issues are of heightened concern among the Reserve as they have more drinking problems5 and interpersonal conflict relative to active duty soldiers post-deployment.6 With more than half of the

Military currently married,1 it is important to examine the potential of a Reservist to influence, or be influenced, by his/her partner. Our previous research,2and that of others, provides evidence that partner influences are powerful predictors of positive or negative changes in health. We also have found that peer networks are involved in changes in alcohol. use among adults11 and that substance use shapes the peer network.12 Social/environmental influences may be particularly salient for Reservists and their partners as social networks change during deployments. These experiences are likely to strengthen the influence of a peer group, particularly if fellow soldiers are within one's peer networks post-deployment. Thus, the proposed study will examine individual and broader social environmental influences (e.g., relationship, community, and societal) on the association between stress and substance use for Reservists and their partners. Using a multi-wave design, Reservists and their partners (N = 400 couples) will be assessed 3 times over 2 years {i.e., baseline, Year 1, Year 2).

Participants will be assessed using state-of-the-science Touch Screen Audio Enabled Computer Assisted Interviews. Using advanced longitudinal analyses (e.g., multilevel and GEE models), this proposal will examine: 1) changes in substance use (alcohol, tobacco, and nonmedical use of prescription drugs) over time in Reserve Soldiers and their partners on the basis of individual (e.g., depressive symptoms), relationship (e.g., partner and peer substance use), community (e.g., workplace/deployments) and societal (e.g., norms) factors; 2) the relation between stress/trauma (e.g., combat exposure/life stress) and substance use; and 3) how the integration of substance use into the relationship impacts marital aggression and dissolution. Importantly, each member of the couple will provide independent data. The proposed study is innovative in: 1) its focus on individual, partner, and peer influences; 2) its focus on Reservists and their partners; and 3) the application of an adapted social ecological model to a Reservist population. The proposed study is significant because it will add to our limited knowledge about the social. {e.g., partner/peer influences) and environmental (e.g., stress/trauma) risk factors for substance use that are faced by Reservists. The knowledge gained from this conceptually and methodologically rigorous study will enhance the development of effective secondary prevention and intervention strategies to address the complex issues faced by military couples.

Example 3: From NIMH sponsored grant 1R01MH099190-01A1 FAMILY OUTLINE OUTCOMES IN AUTISM SPECTRUM DISORDERS

It is now estimated that 1 in 88 children in the U.S. are diagnosed with an autism spectrum disorder (ASD). Few disabilities are more stressful on parents than ASD. There is theoretical and empirical evidence to suggest that chronic parenting stress affects marital adjustment. The overarching goal of this project is to examine the within-family associations between the autism symptoms and behavior problems of children with ASDs and marital adjustment as these processes unfold in naturalistic contexts and across 3 years. The specific study aims are: 1) Compare the self-reported and observed marital adjustment of couples of children with ASDs as compared to couples who have children without disabilities. 2) Test the within-family day-to-day temporal effects of child symptoms and behavior problems on couple interactions. 3) Examine the trajectories of global self-reported and observed marital adjustment across 4 waves of data collection spanning 3 years.

In total, 175 married couples who have a child with an ASD aged 5 to 12 years will participate in the study. Study variables will be assessed through self-reported and teacher-reported measures and direct observations across 4 waves of data collection spanning 3 years. A matched comparison group of 150 married couples of children without a disability will also participate at Time 1 to understand using both a micro-level scale (14-day daily diary at Time 1), to examine the unfolding of 'real time' day-to-day associations in their natural and spontaneous context, and a macro-level scale (4 waves of data collection spanning 3 years), to examine the longer-term time-order pathways between these variables. Our primary unit of analysis is the couple, with individuals (husbands and wives) nested within couples. Multivariate multilevel modeling will be used to handle the inter-dependence of spouses' data collected at multiple time points (Raudenbush & Bryk, 2002) how the processes in families of children with ASDs differ from normative experiences. Associations between marital adjustment and child symptoms and behavior problems will be examined

Example 4: From NHLBI sponsored project 1R01HL114432-01A1 DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES?

Because prior research suggests that resource allocation among parks varies by neighborhood SES, we propose to undertake a national longitudinal study of the existence of disparities in park management practices in 25 representative US cities and 200 parks. In order to advance the state of science on the influence of park management practices on physical activity and park use and to shape public policy on health promotion at the population level, we propose an investigation with the following specific aims: 1) To determine whether there are systematic differences in park resources, programming, management practices, and park use depending upon the socioeconomic status of park neighborhoods in a representative sample of American cities, 2) To determine whether changes in resource allocation among parks in these cities are distributed equally among high and low income parks, or whether allocation changes attempt to address health disparities among potential park users. We will also determine whether changes in resource allocation are accompanied by changes in park-based physical activity, and 3) To make recommendations to the Departments of Parks and Recreation in each city that will support greater use of park facilities among populations who may experience health disparities that can be ameliorated by physical activity. To accomplish the aims of this investigation, we will train a cadre of park professionals and members of community-based organizations that support neighborhood parks to act as "citizen scientists" and collect objective data. Engaging these citizen-scientists in the research process is intended to increase local capacity to reliably measure park management practices, park characteristics, park use, and physical activity. Citizen-scientists are an asset that will endure long after the proposed research (if funded) is completed and could form the basis for research in which future interventions to promote physical activity can be rigorously evaluated. We will also interview key stakeholders to assess other factors that may impact local park use.

KEEP YOUR PROJECT NARRATIVE BRIEF

Direct from NIH: The NIH Application Guides states:

Project Narrative

Provide Project Narrative in accordance with the announcement and/or agency-specific instructions. Please click the Add Attachment button to the right of this field to complete this entry.

For NIH and other PHS agencies applications, using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

If the application is funded, this public health relevance statement will be combined with the project summary (above) and will become public information.

A separate Research Plan form is required for NIH and other PHS agencies applications. Refer to Section 5.5, Research Plan Form, for separate file uploads and instructions.

What this means:

Where the Project Summary/Abstract is 30 lines of text targeted toward scientists in the same field, the Project Narrative is much shorter and serves a completely different purpose, NIH maintains.

The agency states the Project Narrative should be no more than two or three sentences describing your proposed research's relevance to the public health arena. In addition, "in this section, be succinct and use plain language that can be understood by a general, lay audience."

The NIH RePORTER online grant award reporting tool often refers to the Project Narrative as the "Public Health Relevance Statement." It appears below —

and frequently as part of — the Project Summary/Abstract in the RePORTER tool. As such, the Project Narrative will be part of the public record.

> NIAID makes the following suggestions for constructing your Project Narrative:
>
> • In lay language, describe your project's potential to improve public health in two or three sentences.
> • Don't include graphs or other images.

Also, like the Project Summary/Abstract, many grant-writing experts suggest writing the Project Narrative *after* you have completed the bulk of your application. They reason that — at that point — you will have a clearer picture of your proposal's scope and how it impacts public health.

Look at These Examples

With all this in mind, use the following examples of Project Narratives taken from successful NIH grant applications:

Example 1: From NCI sponsored project 1R0CA178980-01 DISPARITIES IN CANCER SCREENING: THE ROLE OF MEDICAID POLICY:

> Low-income women are less likely to receive recommended cancer screenings that can lead to earlier detection and treatment that subsequently reduces morbidity and mortality. This project examines how state Medicaid policies impact breast and cervical cancer screening and related health outcomes among low-income women, and results will help guide strategies to reach under-screened populations and add to evidence regarding the costs and benefits of policies related to Medicaid eligibility, physician payment, and benefit design. Understanding factors influencing screening rates among underserved populations is critical for ensuring efficient use of healthcare resources and reducing inequalities in cancer care and outcomes across socioeconomic and racial groups.

TIP:

Use lay language in your Project Narrative to describe your project's potential to improve public health in two or three sentences.

Example 2: From NIDA sponsored project 1R01DA034072-01A1 SUBSTANCE USE IN RESERVISTS SOCIAL AND ENVIRONMENTAL INFLUENCES

Problematic substance use (alcohol, tobacco, and nonmedical use of prescription drugs) among the US military is of great concern and there evidence that Reserve Soldiers appear to disproportionally shoulder the burden compared to other service members. Understanding the complex relation between substance use, stress/trauma (e.g., combat exposure), and family functioning (e.g., marital aggression) can be helpful for reducing negative impact and improving the health of Reserve Soldiers and their partners.

Example 3: From NIMH sponsored grant 1R01MH099190-01A1 FAMILY OUTCOMES IN AUTISM SPECTRUM DISORDERS

This project contributes to public health by elucidating the pathways by which child stressors related to having a child with an autism spectrum disorder (ASD) impact marital adjustment. Divorce and marital discord have considerable consequences for the psychological and physical health of both adults and children. Understanding how some couples are able to successfully adapt to a stressful family context of having a child with an ASD but others are not has significant implications for improving the psychological and physical health of both parents and the child with an ASD. Our long-term goal for this line of research is to adapt marital therapies to fit the stressful parenting context of ASDs. Findings can also apply to couples of children with other types of behavioral challenges (e.g., attention-deficit hyperactivity disorder or oppositional defiant disorder).

RESEARCH TEAMS FOR SOCIAL AND BEHAVIORAL SCIENCE R01

Many research projects require a team to complete the research. Social and behavioral science R01s often involve multi-disciplinary teams of researchers from several different institutions. Projects that translate research into practice, involve research at a host site like a clinic, hospital or recreational facility, or test a particular product, may want to include practitioner partners from the medical facility hosting the research. Before designing your project, it is important to think about who you will need on your team to achieve your goals. The most successful projects develop their teams before the proposal is developed and involve those partners in developing and writing the proposal.

NIH will want you to include a description of your research team, biographical sketches for key team members, and discussion of how they will participate in the project. It is best to have each team member develop their own biographical sketch, but have the person responsible for the entire proposal and any editors edit the biographical sketch sections for consistency and clarity. Key team members could include co-PIs, research staff that have a management or key analysis role in the project like a project director or the person who does GIS analysis or social network analysis, or practitioners who play a key role in part of the research or translational project.

NIH will want to know three things about your team:

1. Collectively, does the team have the skills and experience to successfully complete the research project?
2. Can this team prove that it has an already established working relationship or can easily develop one?
3. Will each team member have the institutional support they need to complete their share of the work?

These team members may be staff from your institution, partner institutions and/or consultants. The PI can use partners to develop a team that has skills to carry out various components. For example, if the PI is primarily a qualitative researcher, they might include a co-PI that is an expert on survey research or social network analysis. If the project involves multiple sites, co-PIs may have similar skills, but be affiliated with institutions in each location participating in the research project. Junior researchers might include a senior colleague as a co-PI or consultant to show that someone with significant expertise and a track record of successful project completion is involved in the initiative.

Projects including clinical components may include clinicians who design and carry out the clinical pieces of the research. Projects that use clinical facilities to identify research subjects may have a clinician partner whose primary role involved identifying participants for the research project, then is an active participate in analyzing the results and developing the clinical or translational findings from the project. For example, a study of caregivers of cancer patients may have a clinical partner who helps the research team develop a list of potential caregiver participants and encourages them to participate. Once the researchers have completed data collection, the clinical partner would participate in the analysis and develop ways that the findings could be used in medical facilities.

Key staff includes both those leading the various components of the project and individuals with specific roles necessary to carry out the research. Several program officers reported that they want an application to include information on a project director, coordinator or manager who will be responsible for overall day-to-day management of the project. Even though this person may be a junior faculty member, post-doc or graduate student, their work will be important to the success of the project. Like co-PIs, their biographical sketch should demonstrate that they have the skills and experience to carry out their work.

Peer reviewers often look for established relationships among key members of the research team. This may include having developed other projects together or

being part of a research collaborative focused on a similar topic. Since R01s need pilot data or other research as a basis for their application, the key team members, particularly PI and co-PIs can show that they have worked together by developing a pilot project together. If they have done similar work, but have not worked together previously, it may be wise to write a research paper based on data collected by each partner and publish it before applying for an R01 grant. Collaborators can show ongoing relationships through conference panels developed together, participation in formal research collaboratives, or other working relationships. Clinical partners may have worked with the PI on a policy forum, quality assurance initiative, or other committee activity. The point is to show that the partners have worked together in the past successfully.

This means that if you want to add someone to your project that you have not worked with before, you may need to wait to submit your application until you can demonstrate an established relationship. This does not mean that you will have to work with someone for years before applying for a grant with them, but that you will need time to successfully complete a collaborative activity with them. For example, one PI moved to a new university between receiving scores for her R01 application and resubmitting it. Since she planned to include co-PIs from her new institution on the project, she performed some additional pilot research with her new co-PI and published that research before resubmitting the application.

Key staff information should be included in several places in the application:

1. **The cover sheet,** where each key team member is listed
2. **Team member biographical sketches:** Biographical sketches should include the person's role in the project and why this person the right person for this role. It is also important to mention any previous collaborations between this key person and the PI or other members of the team. These relationships can be documented in both the personal statement and published works sections.

3. **Facilities and other resources:** Projects involving several institutions may submit a facilities and other resources section that outlines not only the space and equipment available at each facility, but the people involved there and what they will do.

For example, a clinical trial of a behavioral science intervention (grant 1R01AA021136-01A1) included seven co-investigators from two academic institutions and a medical center. Several Centers and Departments at each university were involved. In the facilities and resources section, the application included a brief description of the key personnel that work at each institution.

4. **Budget justifications:** Descriptions of the amount of time each key researcher spends on the project and what they will be doing to support the project.

5. **Subcontract justifications:** Brief discussion of why each subcontracted partner institution is included and what personnel will be located there.

6. **Support letters:** Letters from each key staff researcher or consultant explaining both why they think the project is important and how they will contribute to the project.

7. **Research plan (appendix):** Outline of how the research will be conducted and who will be responsible for each part. Research plans may include timelines, flow charts or other diagrams that outline the various components of the project, when each occurs, and who is responsible for each component. Key staff are listed under the pieces of the project they will be involved in. While research plans can be incorporated into the description of the research in the body of the proposal, they are often attached as an appendix.

USE ALL THE PARTS OF THE BIOGRAPHICAL SKETCH

Researchers with previous experience writing grants to NIH will be familiar with the old biographical sketch format in effect until May 24th, 2015. NIH has changed its format and the agency's plan to modify the current biosketch format is scheduled to roll out for all grant applications received for FY 2016 funding and beyond (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-091.html). This means that any grant submitted for due dates on or after May 25th, 2015 will need to use the new format (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html). For more detailed information on the new biosketch format and creating a database of your publications in the approved format see [https://principalinvestigators.org/product/nih-biosketch-guide/]. In summary, these changes include:

- Increasing the total biosketch length to five pages, instead of four
- There is a new Section C - Contributions to Science. This section will succeed the Selected Peer-Reviewed Publications section. In this new Section C, applicants will briefly describe up to five of their most significant contributions to science. Each description should be no longer than one half page, including figures and citations. For each contribution, the applicant will reference up to four peer-reviewed publications relevant to that specific contribution. Be sure to provide a URL to a full list of your published work as found in a publicly available digital database such as PubMed or My Bibliography.

Why change the format?

The purpose of these changes has best been summarized by Dr. Sally Rockey, NIH's Deputy Director for Extramural Research. Her complete web posting on this subject may be found at http://nexus.od.nih.gov/all/2014/05/22/changes-to-the-biosketch/:

The primary focus of the new NIH biosketch will be the magnitude and significance of the scientific advances associated with a researcher's discoveries and the specific role the researcher played in those findings. This change will help reviewers evaluate you not by where you've published or how many times, but instead by what you've accomplished. Hopefully, this change will redirect the focus of reviewers and the scientific community more generally from widely questioned metrics, like the number of published papers, the number of citations received by those papers, or one of several statistical approaches used to normalize citations.

We strongly believe that allowing a researcher to generate an account of his or her own work will provide a clearer picture of each individual's contributions and capabilities. But one might question whether this new biosketch will have a negative impact on younger investigators whose body of work may not be as robust as more established investigators. I believe the contrary is true; this new format will give early career investigators a platform for describing and framing the significance of their contributions, which should help reviewers better understand their accomplishments without having to rely simply on a list of publications.

Direct from NIH: The NIH Application Guides states:

Provide a biographical sketch for the senior/key person. Recommended information includes: Education and Training, Research and Professional Experience, Collaborators and Affiliations (for conflicts of interest), Publications and Synergistic Activities. Save the information in a single file and attach here. This is required information.

What this means:

NIH limits the Biographical Sketch — also known as the Biosketch — to no more than five pages per person and provides a form for presenting this information. Your application must include a complete Biosketch for all Senior/Key Personnel and Other Significant Contributors.

NIH defines Senior/Key Personnel as the Project Director (PD)/Principal Investigator (PI) "and other individuals who contribute to the scientific development or execution of the project in a substantive, measureable way, whether or not salaries or compensation are requested under the grant." Usually, these Senior/Key Personnel have doctoral or other professional degrees, NIH says, adding that you should also include those with master's and baccalaureate degrees if their involvement meets the above definition.

You will also need a Biosketch for any Other Significant Contributors, those persons who commit to contribute to the project's scientific development or execution, NIH states. They are usually listed as presenting "effort of zero person months" or "as needed" on your application. Consultants likely will be in this category.

REMEMBER:

The Biosketch is your opportunity to detail your knowledge, skills and ability to perform your proposed research.

The Biosketch is your opportunity to detail your knowledge, skills and ability to perform your proposed research. Demonstrate that you are the individual most qualified to do it. Reviewers scrutinize this section to ensure that you and other investigators and proposed staff have the proper experience with the proposed techniques.

Although NIH limits the Biosketch to five pages per person, the form for this portion is only the first page and provides space only for the key personnel's education. You then add up to four additional pages to complete the individual's Biographical Sketch. NIH additionally instructs you to complete this information "beginning with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training, separately referencing residency training when applicable."

OMB No. 0925-0046 (Approved Through 5/31/2016)

BIOGRAPHICAL SKETCH—*Pilot Format (To Be Used for Specific FOAs only)*

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME	POSITION TITLE
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY

NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

What Your Biosketch Should Include

Direct from NIH: The NIH Application Guides states:

A. Personal Statement

Briefly describe why you are well-suited for your role in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Contribution to Science

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

Don't confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, "Other Support" information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date "other support" information from you after peer review. This information will be used to check that the proposed research has not already been Federally-funded.

What this means:

The Biosketch must include the following sections, but keep in mind that it cannot exceed five pages:

- **Personal Statement** — Here, you should briefly describe why your experience and qualifications make you particularly well-suited for your role (such as Principal Investigator, mentor, etc.). You should create a new personal statement for each application you write that is tailored to that application. Under this section you can also include:

  - **Peer-Reviewed Publications and Manuscripts in Press relevant to this grant** (in chronological order) — NIH indicates that you should not include manuscripts submitted or in preparation, but you may choose to include selected publications based upon recency, importance in the field and/or relevance to the proposed research. Additionally, if the article falls under the Public Access Policy, was authored or co-authored by the applicant and arose from NIH support, you need to provide only the NIH Manuscript Submission reference number or the PubMed Central (PMC) reference number.

- **Positions and Honors** — List your previous positions in chronological order, concluding with your present one. Also, list any honors and include any memberships on federal government public advisory committees.

- **Contributions to Science** – List up to five examples of project findings or concrete translational products that made a significant contribution to either the science in your field or improved health or public health. This could be an article that is regularly cited and changed how scholars think about the field or research that resulted in a change to care or understanding of a public health problem.

> • **Research Support** — For this section, list both selected ongoing and completed (during the last three years) research projects. Begin with the most relevant to your current proposal, and briefly state the project's overall goals and the responsibilities of the Senior/Key Personnel. Keep in mind that this is not the place for the number of person months or direct costs.

Now, let's look at the Biosketch parts one at a time to show how they will affect your application.

Personal Statement

The Personal Statement should detail why you are the best individual for a role in the project.

Reviewers now consider the information you include here when they examine your qualifications. These may include your pedigree, your research experience or your track record of resolving challenges in new areas. You need to point out specifically why you think you are the most qualified person to lead your proposed project.

At the same time, you should avoid sounding as if you are boasting. Instead, reference specific objectives and criteria in your background, grants you have already been awarded and publications that resulted from those grants.

Point to presentations you gave, address changing fields of study, and if you are a new investigator — but not an early-stage one — you can detail your experience working in a national laboratory.

If you have been in the research field for years but never had an NIH grant, the Personal Statement is where you can clearly note that, although you are new to this funding source, you are not an early-stage investigator. That is an important distinction reviewers need to know.

STRATEGY:

In your Personal Statement, reference specific objectives and criteria in your background, grants you have already been awarded and publications that resulted from those grants.

NIH instructs reviewers to be less stringent when judging preliminary data from early-stage investigators because they have not had the resources to perform preliminary research. Reviewers would rather judge you on your track record as a postdoctoral researcher than as a graduate student.

New Investigator Case Study

A Principal Investigator (PI) returns to academia from a successful career as a medical director in a major behavioral health company, having managed annual budgets up to $100 million. Prior to that, the PI was in the NIH Intramural Program at the NIH hospital for 10 years and was awarded NIH tenure decades ago. The PI is also a member of the Institute of Medicine. On the other hand, the PI has never received an NIH grant because funding always came from other sources. In that sense, the PI is a new investigator.

The best way to leverage this PI's unusual background to obtain NIH grant funds is by making it explicitly clear in the Personal Statement. By referencing such items as IOM membership, tenure in a very competitive environment, and responsibility for $100-million projects, the PI in this example demonstrates her competence, experience and track record to NIH reviewers who are predominantly from academia.

This PI would qualify for the new investigator category, but would not receive any breaks because of "lack of experience." At the same time, she may be given some leeway in terms of presentation because reviewers would recognize that she was not used to following the NIH format. The PI would be judged as the senior investigator that she is.

Early Investigators Stress Independence

Early investigators, obviously, should take a different tack. In particular, they should stress their independence from others at their institutions if they will perform their research in that setting and want the NIH to fund it.

TIP:

Early investigators should stress their independence from others at their institutions if they will perform their research in that setting and want NIH to fund it.

As a result, reviewers suggest that the early investigator's Personal Statement should include such language as the following:

- "Although I received my training at this institution, I have established an independent community outreach program that provides the host site for this research."
- "I have been the intellectual behind the project for the last year."
- "I wrote the grant proposals."
- "My former mentor is going in a different direction."

In addition, including a letter from the former mentor would help reinforce that the early investigator is independent and delineate the differences between what he is doing now and what the mentor is continuing to do.

Another key issue for early investigators is the degree of institutional commitment in their department or research center and their position within the organization. For example, an assistant professor who is expected to teach five large survey courses with a department chair that refuses to approve course releases or let him teach graduate courses which would automatically lower his teaching load would not be a good candidate to successfully complete a research project.

Before submitting your project, you will need to get a written commitment from your department chair, center director, dean and any other relevant administrative staff that you will receive the course reductions you need to complete the project if you receive funding. If your research project calls for students in a class to conduct some of the research as a service learning project, it is wise to get a written guarantee from both your department chair, dean, and any administrative staff responsible for research that the class will be offered, regardless of enrollment size or any other university rules that could cancel a previously scheduled class. If your research requires a graduate assistant paid for as a match by the university, it is helpful to get a support letter guaranteeing this support. These kinds of supports will be outlined in the facilities and research support section of your proposal.

The stronger you can indicate your institution's backing for your research proposal, the better your application will fare. Even if you are funded for a project, if your department chair or administrative staff sabotage your first project through failing to provide promise resources, you will have great difficulty succeeding. NIH and reviewers may be sympathetic to researchers with unsupportive departments or administration, but they are less likely to fund them the next time they submit a proposal.

Addressing Impediments to Productivity

The NIH format for the personal statement allows the researcher to explain why they may not have had an unbroken track record of successful research. This new potential component is designed to level the playing field for women, people with disabilities, and people who served in the armed services – all groups that are generally under-represented as successful NIH researchers. These groups may have faced special challenges in maintaining a regular research schedule or publishing their work. For instance, someone who took time off to care for young children or a sick relative, or someone who had a serious illness that kept them from working for several years, can explain the gap in their work history. A person with a disability may have had trouble obtaining positions in research institutions due to discrimination or simply may need to take more time to complete research or publications due to the nature of their disabilities. The same would be true for someone who completed their post doc, then served in the military for several years or someone who was in the reserves and was called up to several tours of active duty which interfered with completing an earlier research project.

This section is not the place to explain that your research or publication productivity has been low because your department chair sabotaged your work or your teaching load is too high to find time to write publications. Or that you have to work two jobs because of low pay as an assistant professor in a community college. This only suggests that you do not have the institutional support to successfully complete an NIH grant. The only time this might be worth mentioning is if you had a strong track record before taking a job in an unsupportive institution, and

have now changed jobs. In that case, a statement like, "As shown by my early work including [list of NIH funded projects], I have made significant contributions to the study of disease X. My recent move to university Y allows me to continue my earlier work through this new study."

Whatever the reason for the impediment in productivity, it is always important to express any challenges in a positive light. For example,

> *While my research productivity has been less for the past three years given the birth of two children for which I am the primary caregiver, I have completed a pilot project and published the results in [journal].*

> *Due to challenges related to disabilities, I have had trouble finding a full time position that would provide support to my research. Despite these impediments, I succeeded in completing projects [list of projects], which contributed to understanding of disabling condition X. As a person with a disability, I am in a unique position to study condition X. My current position at Institute A will provide the support I need to further my work through this project.*

> *After successful completion of my post-doc, I served for three years as an active duty officer in the military. This experience has given me unique insights into the social conditions of returning soldiers and will benefit my ability to complete this project.*

Get Creative

The Personal Statement offers you the opportunity to clarify who does what — and who pays for what — in a series of experiments involving multiple personnel and funding sources.

Case Study 1: A junior investigator has a K01 grant — for which you, as the Principal Investigator on a renewal R01 grant, are the sole mentor — that has overlapping aims with your renewal R01. The K01 mainly supports salary and not the entire support infrastructure. The R01 has many more aims, but some overlap with the K01. In this case, the question becomes: Should you list the K01 recipient as Senior/Key Personnel or Other Significant Contributor on your R01 if you are not going to use any funding for your proposal as salary for this individual?

For this case, because the K01 is a training or transition grant, you would simply need to explain the relationship between the K01 grant and the parent R01 in your Personal Statement and possibly in the Environment statement because the K01 recipient is a positive feature of the environment. The K01 recipient should complete a Personal Statement for the R01 application as an Other Significant Contributor and use it to explain the relationship between the two grants. You should also explain the salary support issue in the Budget Justification section of the R01 application.

Case Study 2: You have a K award for a small randomized controlled trial on an intervention you developed and will soon submit an R01 application that builds on the data you have collected as part of it. In this case, the questions regarding your Personal Statement become:

- Should you emphasize your status as an early-career and new investigator?
- Should you emphasize how the pilot data were collected as part of the K award?

Here, you should discuss your background, which should clearly reflect your status as both an early-stage and a new investigator. You have already succeeded in the competitive grants environment by receiving a K award and then successfully used that K award to generate experimental results that will lead directly to a larger project of increased scope. Be sure to clearly indicate how your prior work is directly related to and effectively supports the work you propose in the R01. Highlight your ability to think strategically to consider the next question to be answered and how that impacts your proposal.

Personal Statement Examples

NIH does not specify whether to write the personal statement of the biosketch in 1st or 3rd person. As such, they provide examples to illustrate both (http://nihgrants.blogspot.com/2011/06/nih-biosketch-personal-statement-first.html):

First Person:

Personal Statement

The goal of the proposed research is to investigate the interaction between drug abuse and normal aging processes. Specifically, we plan to measure changes in cognitive ability and mental and physical health across a five-year period in a group of older drug users and matched controls. I have the expertise, leadership, and motivation necessary to successfully carry out the proposed work. I have a broad background in psychology, with specific training and expertise in key research areas for this application. As a postdoctoral fellow at Berkeley, I carried out ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. At the Division of Intramural Research at the National Institutes on Drug Abuse (NIDA), I expanded my research to include neuropsychological changes associated with addiction. As PI or co-Investigator on several previous university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant in the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time. In addition, I successfully administered the projects (e.g., staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work, and I have chosen co-investigators (Drs. Gryczynski and Newlin) who provide additional expertise in cognition, gerontology, and geriatrics. In summary,

I have a demonstrated record of successful and productive research projects in an area of high relevance for our aging population, and my expertise and experience have prepared me to lead the proposed project.

Third Person:

Personal Statement

The goal of the proposed research is to investigate the interaction between drug abuse and normal aging processes. Specifically, the research team plans to measure changes in cognitive ability and mental and physical health across a five-year period in a group of older drug users and matched controls. Dr. PI has the expertise, leadership and motivation necessary to successfully carry out the proposed work. She has a broad background in psychology, with specific training and expertise in key research areas for this application. As a postdoctoral fellow at Berkeley, Dr. PI carried out ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. At the Division of Intramural Research at the National Institute on Drug Abuse (NIDA), she expanded her research to include neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, she laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time. In addition, Dr. PI successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, Dr. PI is aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on her prior work, and she has chosen co-investigators (Drs. Gryczynski and Newlin) who provide additional expertise in cognition, gerontology and geriatrics. During 2005-2006, Dr. PI's career was disrupted due to family obligations. However, upon returning to the field, she immediately resumed her research projects and

collaborations and successfully competed for NIH support. In summary, Dr. PI has a demonstrated record of accomplished and productive research projects in an area of high relevance for our aging population, and her expertise and experience have prepared her to lead the proposed project.

Peer-Reviewed Publications and Manuscripts in Press

STRATEGY:

NIH reviewers suggest that, if you have numerous publications to your credit, you should select 4 that are most recent, most important to your field, and most relevant to your proposed research. Remember, you will list all of your publications in a database available to the reviewers.

Many applicants struggle to choose their top publications to support their experience and ability. Remember that you should be choosing publications most related to this research project. Criteria include most recent, most important to your field, and most relevant to your proposed research.

On the other hand, if you think your 4 most recent do not demonstrate your strength as an investigator, you should go back to older publications and use those that demonstrate the following:

- That you have previously worked in the field;
- That you have a successful track record in several different fields; and
- That you have made an impact in your field.

NIH stresses that any publication that is in PubMed should have its publication citation code and that you should not include publications in your appendices. For social scientists who publish in respected journals not in PubMed, these codes will not be available. When choosing publications and creating citations, remember:

- As for adding the PMCID codes, it is the law. NIH could "withdraw you administratively," using government funding agency language, if you fail to include this information.
- Regarding publications in your appendix materials, regulations state that you should include only those that are not publicly accessible on the Internet. Therefore, include only those that are "in press" and not yet published online.

The publications list also allows you to demonstrate that you have a track record as a successful researcher. R01 grant applications are limited to 12 pages so you do not have much space to provide the background or experimental details or to present 35 figures of preliminary data.

The Biographical Sketch(s) does not count toward the 12-page limit. So you should reference your published papers that demonstrate feasibility and your track record, and then use your application to present only those figures that have not been published and demonstrate key points. This would include the key scientific points that establish your hypothesis' validity or key technical points that demonstrate your approach's feasibility.

The publication list is also an ideal place to show previous collaboration with any co-investigator(s) you will be working with under the new proposal. In fact, NIH reviewers indicate that showing you have a history of working with the collaborators is "very important," and the publication list is "one of the cheapest places to demonstrate that."

In fact, you may be better served to sacrifice some of your more impactful publications to include a few that indicate you have worked with the proposed collaborators. You can then add a sentence that says, "This team includes collaborators who have worked together in the past and published X number of papers, as demonstrated below."

Reviewers generally have reduced enthusiasm for many collaborative proposals because of insufficient evidence that the researchers have previously worked together. For example, if one collaborating researcher is in Philadelphia and the other is in Washington, D.C., the reviewer will want to know that you have already discovered ways to bridge the geographical distance. Co-authored publications are one tool to convince reviewers that you make a successful team.

TIP:

You may be better served to sacrifice some of your more impactful publications to include a few that indicate you have worked with your proposed collaborators.

Learn From This Example

NIH provides the following example of a personal statement and publications:

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

1. Merryle, R.J. & Hunt, M.C. (2004). Independent living, physical disability and substance abuse among the elderly. Psychology and Aging, 23(4), 10-22.
2. Hunt, M.C., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-dwelling elderly. International Journal of Geriatric Psychiatry, 24(9), 1124-1135.
3. Hunt, M.C., Wiechelt, S.A. & Merryle, R. (2008). Predicting the substance-abuse treatment needs of an aging population. American Journal of Public Health, 45(2), 236-245. PMCID: PMC9162292 Hunt, M.C., Newlin, D.B. & Fishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. Gerontology, 46(3), 122-145.

Positions and Honors

This section of the Biographical Sketch is rather straightforward. Here, you should list your employment history — that is, dates, places and the nature of the positions. In addition, include any honors and memberships on any federal public advisory committees.

NIH provides the following example:

Positions and Honors

Positions and Employment

1998-2000 Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD

2000-2002 Lecturer, Department of Psychology, Middlebury College, Middlebury, VT

2001- Consultant, Coastal Psychological Services, San Francisco, CA

2002-2005 Assistant Professor, Department of Psychology, Washington University, St. Louis, MO

2005- Associate Professor, Department of Psychology, Washington University, St. Louis, MO

Other Experience and Professional Memberships

1995- Member, American Psychological Association

1998- Member, Gerontological Society of America 1998- Member, American Geriatrics Society

2000- Associate Editor, Psychology and Aging

2003- Board of Advisors, Senior Services of Eastern Missouri

2003-2004 NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer

2005-2009 NIH Risk, Adult Addictions Study Section, member

Honors

2003 Outstanding Young Faculty Award, Washington University, St. Louis, MO

2005 Excellence in Teaching, Washington University, St. Louis, MO

2008 Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

Contributions to Science

NIH provides the following guidelines for section C:

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.

What this means:

NIH wants you to show that you have done research that has had a significant impact on both your scientific field and health or public health. In order to demonstrate your ability to conduct significant research with real impact, they ask you to choose four projects and explain in plain language, what you did, what you found, and its impact on the scientific field you study and/or health or public health.

You should list four publications for each project. This is a way to highlight more of your successful publications and you should use the same criteria for choosing publications related to each project as those you highlight in the personal

statement. The ones in the personal statement should be most closely related to the project you are currently seeking to fund.

NIH now also requires that you provide a full list of your publications in a publically available database. In reality, this means that you should use one of the two database programs that they mention in the application   SciENcv or My Bibliography. Detailed directions on these programs are available in [https://principalinvestigators.org/product/nih-biosketch-guide/]. Entering data into these databases may be time consuming, so be sure to allow the time or find a graduate student or clerical staff person willing to do it for you.

The NIH provides the following example of the new Section C:

C. Contributions to Science
1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.

    a. Gryczynski, J., Shaft, B.M., Merryle, R., & Hunt, M.C. (2002). Community based participatory research with late-life addicts. American Journal of Alcohol and Drug Abuse, 15(3), 222-238.

b. Shaft, B.M., Hunt, M.C., Merryle, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. International Journal of Drug Policy, 30(5), 46-58.

c. Hunt, M.C., Marks, A.E., Shaft, B.M., Merryle, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. Journal of Applied Gerontology, 28(2),26-37.

d. Hunt, M.C., Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2007). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. Addiction, 104(9), 1436-1606. PMCID: PMC9000292

2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older substance abusers and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiology and maintenance of addictive disorders and the disruptive potential of networks in substance abuse treatment. This body of work also discusses the prevalence of alcohol, amphetamine, and opioid abuse in older adults and how networking approaches can be used to mitigate the effects of these disorders.

a. Hunt, M.C., Merryle, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. Journal of the American Geriatrics Society, 57(4), 15-23.

b. Hunt, M.C., Pour, B., Marks, A.E., Merryle, R. & Jensen, J.L. (2005). Aging out of methadone treatment. American Journal of Alcohol and Drug Abuse, 15(6), 134-149.

c. Merryle, R. & Hunt, M.C. (2007). Randomized clinical trial of cotinine in older nicotine addicts. Age and Ageing, 38(2), 9-23. PMCID: PMC9002364

3. Methadone maintenance has been used to treat narcotics addicts for many years but I led research that has shown that over the long-term, those in methadone treatment view themselves negatively and they gradually begin to view treatment as an intrusion into normal life. Elderly narcotics users were shown in carefully constructed ethnographic studies to be especially responsive to tailored social support networks that allow them to eventually reduce their maintenance doses and move into other forms of therapy. These studies also demonstrate the policy and commercial implications associated with these findings.

   a. Hunt, M.C. & Jensen, J.L. (2003). Morbidity among elderly substance abusers. Journal of the Geriatrics, 60(4), 45-61.

   b. Hunt, M.C. & Pour, B. (2004). Methadone treatment and personal assessment. Journal Drug Abuse, 45(5), 15-26.

   c. Merryle, R. & Hunt, M.C. (2005). The use of various nicotine delivery systems by older nicotine addicts. Journal of Ageing, 54(1), 24-41. PMCID: PMC9112304

   d. unt, M.C., Jensen, J.L. & Merryle, R. (2008). The aging addict: ethnographic profiles of the elderly drug user. NY, NY: W. W. Norton & Company.

   Complete List of Published Work in MyBibliography:
   http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1PgT7IEFIAJBtGMRDdWFmjWAO/?sort=date&direction=ascending

When writing this section, keep the following in mind:

- What do you consider your most significant contributions to science? This can be contributions to science in general, to a specific scientific discipline, or a combination.
- The background for the scientific question or problem you are highlighting in each contribution.

- A recap of the critical findings for each.
- How these findings were used to guide future progress in addressing health-related problems or advancing technology
- What was your specific role in the described work?

Research Support

In the Biosketch's Research Support section, you should list both ongoing and completed projects, including those with both federal and non-federal funding. Start with the projects most relevant to the current application and briefly indicate their overall goals and responsibilities of the Senior/Key Personnel involved in the current proposal. This, however, is not the place to detail the number of person months and direct costs.

Be sure not to confuse "Research Support" with "Other Support." Although they may sound similar, these parts of the application are quite different. The Biosketch's Research Support section highlights your scientific accomplishments and your role in selected grants. Reviewers will use this information to assess each individual's qualifications for a specific role in the project, as well as their roles on the research team.

The Other Support section, on the other hand, includes information required for all applications that are selected to receive awards. NIH staff will request complete and up-to-date Other Support information from awarded researchers after peer review and then check this information to ensure that the proposed research has not already been federally funded.

NIH provides the following directions for this section in the new biosketch directions:

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

NIH provides the following example of the Research Support portion of the Biosketch:

2. Research Support Ongoing Research Support

R01 DA942367-03   Hunt (PI)   09/01/07-08/31/12

Health trajectories and behavioral interventions among older substance abusers. The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.
Role: PI

R01 MH922731-05   Merryle (PI)   07/15/05-06/30/10

Physical disability, depression and substance abuse in the elderly. The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.
Role: Co-Investigator

Faculty Resources Grant, Washington University   08/15/09-08/14/11
Opiate Addiction Database

The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.

Completed Research Support

K02 AG442898   Hunt (PI)   09/01/06-08/31/09

Drug Abuse in the Elderly

Independent Science Award: to develop a drug addiction research program with a focus on substance abuse among the elderly.

Role: PI

R21 AA992075   Hunt (PI)   01/01/04-12/31/06

Community-based intervention for alcohol abuse

The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.

Role: PI

LETTERS OF SUPPORT ARE AN IMPORTANT COMPONENT OF YOUR PROJECT

Letters of support provide documentation that you have developed the relationships you need to support your project. Support letters indicate commitments of resources or personnel to a project. They can also indicate that specific organizations that can help disseminate findings plan to use study results. For new investigators, they can be testimonials from mentors or senior colleagues indicating that the PI has the skills and characteristics to successfully carry out an R01 project.

REMEMBER:

Letters of support do not fall within the NIH's application page limit, so you can include as many as you feel are necessary.

NIH allows as many letters of support as the investigator feels are necessary to show that the project has the resources it needs to accomplish its goals. It is important to include support letters from any person or organization that is participating directly in the project. You want enough support letters to show that you have the relationships necessary to carry out the work and, if you are a new investigator, that others think your research is important. Generally, support letters come from three different types of people or institutions:

1. **Participating people or institutions:** These would include support letters from co-PIs at other institutions, consultants, or clinical staff carrying out part of the project. Institutions that will be subcontractors on a multi-site project or hosting a project should also provide support letters. For example, if your application was developed in partnership with another university and would be conducted at hospitals near both institutions, you would want support letters from your co-PI at the other university, a second support letter from his/her university, and support letters from high level administrators at both participating hospitals.

2. **Organizations benefiting from your research or committed to disseminating results.** These kinds of support letters show that the end users of your research think it is important and are invested in sharing it. These general support letters are usually included with projects that have

direct translational components or are testing a new tool, protocol or device. They are most useful if they indicate a direct interest in using the results of the study. For example, if you are developing a new protocol to clarify the types of resources available to families of transition age youth with autism, a support letter from a local school district or the regional ARC chapter saying that they think your research is important and that these organizations plan to use your new protocol in their programs would be a powerful indicator of the potential impact of the results of your R01 project.

3. **Senior colleagues with standing who can confirm that you can successfully complete an R01 project.** These letters should only be included with applications from new investigators. They are usually from mentors or senior colleagues familiar with your work, who are well known, and respected in the NIH research community. The colleague may have a small role in the project as an advisor or co-PI. These letters are designed to indicate their knowledge of your abilities and encourage reviewers to consider the project.

While it is helpful to include support letters from organizations not involved in your project that could benefit from your work or senior colleagues, you should not include too many of these letters. One or two support letters indicating that your work will have impact on health or public health could help readers understand the impact of your work. That said, busy reviewers may not have time to read through support letters and including a large number may overwhelm them. One or two good letters of support from supporters not directly involved in the project are usually sufficient.

Direct from NIH: The NIH Application Guides states:

> Attach all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants)

TIP:

One or two support letters indicating that your work will have impact on health or public health could help readers understand the impact of your work.

not contributing in a substantive, measurable way to the scientific development or execution of the project. Letters should stipulate expectations for co-authorship, and whether cell lines, samples or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only. For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service. Do not place these letters in the Appendix. Consultant biographical sketches should be in the Biographical Sketch section.

What this means:

NIH wants you to include a support letter from any consultants, co-PIs, research consortium, partnering institutions, and any other organization that plans to either host research, help you find research participants, or use/disseminate the results or products of your project. These letters should not be vague statements of the importance of your work. Instead, they should indicate to NIH exactly what the person or organization providing the support letter intends to do for the project and why they think the research is important. This means that consultants, co-PIs, co-PIs universities or institutions, and any organization hosting or facilitating your research needs to provide a support letter showing their role in the project. These letters indicate commitment to participate in the project should it be funded.

These letters should be included as attachments in the application, not as an appendix. It is important to include them as attachments because otherwise reviewers are less likely to read them.

TIP:

You can write a desired draft of a letter of support for the person to review and sign, but do not make all of your supporting letters look the same.

The letter should specify what support the person is offering, and it must be plausible. You can write a desired draft for the person to review and sign, but do not make all of your supporting letters look the same. Take the time to determine what aspects of your proposal would be most interesting and relevant to each of your collaborators.

This support letter, from NHLBI sponsored project 1R01HL114432-01A1 DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES?, provides an example of letters written by organizations intending to contribute to the project by hosting researchers and disseminating results. Names have been redacted to protect privacy:

Dear PI:

City Parks Alliance, the only independent nationwide membership organization solely dedicated to urban parks, is pleased to support the proposed NIH grant application to measure health outcomes related to comparative park quality in medium- low-and very-low-income neighborhoods.

This groundbreaking research project would involve our extensive network of public and non-profit park organizations in cities nationwide and enable us to gather much needed data to better understand the relationship between park access and use and neighborhood socio economic conditions.

The data collection would help us identify barriers to park use based on real or perceived safety threats, programming, staffing, park size and proximity. The effort would also provide an extraordinary opportunity to connect research and policy as we work to. Advance system-wide, equitable approaches to park and recreation planning, programming, operations and funding in urban communities.

We look forward to partnering with [Institute] on this important and much needed study,

Best regards,
Executive Director

This letter, provided by a consultant who is also a senior scholar in the field, provides information on a consultant with specific expertise from the institution where the research will be carried out. This example shows both a letter from a key staff person and a letter from a senior colleague for a new investigator. It comes from NIDA sponsored project 1R01DA034072-01A1 SUBSTANCE USE IN RESERVISTS SOCIAL AND ENVIRONMENTAL INFLUENCES:

Assistant Professor, Department of Community
 Health and Health Behavior School of Public
 Health and Health Professions

RE: Letter of Support

Dear Dr.:

Thank you for the invitation to consult on your DOD grant application entitled "Stress and Substance Abuse among Reserve Soldiers and their Spouses: Social and Environmental Influences." Understanding substance use patterns, as well as the role of stress and trauma among military reservists and their partners is important for not only prevention efforts but also for treatment efforts. I believe that you have a strong team of co-investigators, and important and relevant research aims that could add significantly to our knowledge about the health of our military. Importantly your work recognizes the value of considering the role of intimate partners and the social network on changes in substance use and health over time.

As you know, I served 25 years as a research psychologist in the Army, during which time I conducted numerous field studies of stress, health and adaptation among military personnel and their families. These research projects covered military deployments ranging from the Gulf War to Bosnia and more recent operations in Iraq and Afghanistan. My previous assignments included five years as Commander of the U.S. Army Medical Research Unit-Europe (Walter Reed Army Institute of Research) in Heidelberg, Germany. I am a past-President of the. Society

for Military Psychology, Division 19 of the American Psychological Association. My professional training and military experiences make me well suited to consult with you on issues related to the military, stress, and family life among our servicemen and women.

I understand we will consult on your project via phone and email on an "as needed" basis in all years of the grant; however, in years I and 4 we will have more regular contact as project startup l and wrap-up tend to involve more issues. In these years, I will be available to you for [Redacted % Effort] days each year at a rate of [Redacted] per day. I look forward to collaborating with you and the other investigators on this important project.

<div align="center">Sincerely,</div>

While you should not write letters of support, you should provide those writing support letters drafts of what you want that include places for them to add details related to their institutions or role in the project. Here are four reasons you should craft the initial draft of your letters of support:

- **Congruence.** You know your grant application strategy best, so your self-written draft letter of support becomes part of that overall strategy. Communicating to others exactly what you need and what to cover — and then asking them to prepare it — can be difficult and time-consuming. If you do it for them, you establish momentum and eliminate any breakdown in communication.

- **Expectations.** Initial conversations with contractors and collaborators when you request letters of support may leave both sides with faulty assumptions regarding what to include. When they see your expectations in the letter you construct for them, however, you avoid potential misunderstandings. This ensures that everyone is "on the same page" from the beginning.

- **Timeliness.** Your grant application is a high priority for you, and you are well aware of any deadlines. But your collaborators and contractors may not have the same priorities, and your letter of support may drop lower on their to-do list. When you offer to write the letter, you likely will receive a quicker response that meets your deadlines.

- **Facilitation.** Allowing your contractors and collaborators to edit your letters is easier for them than drafting the letters on their own. They can read your letter and offer comments and clarifications without having to start from scratch.

Keys to Crafting Effective Letters of Support

When you write a letter of support, here are a few tips to keep in mind:

1. **Clarify duties, roles and timelines.** Offer specific details regarding what you expect the collaborator or contractor to do, as well as the deadline. This will avoid potential misunderstandings later. And when individuals other than the applicant write their own letters of support, they are often more vague than what the applicant needs. Therefore, make sure the letter draws attention to what you, as the applicant, have done that is relevant to any NIH requirements — or those of any ICOs that may potentially review it.

2. **Write it from the contractor or collaborator's point of view.** Tailor each letter to the collaborator or contractor's specific duties, and write it as if they wrote the letter. If you prepare more than one letter, make sure to use unique language for each. Host sites should discuss their mission and benefits of the project to their mission.

3. **Display enthusiasm.** The letter should convey the individual's enthusiasm for the project by outlining specifics, such as resource and time commitment and interest in the project's details.

4. **Get the standard details correct.** Address the letter according to the grant's guidelines. It will be going to either the applicant or NIH. Have the final, agreed-upon version written on an institutional letterhead, and have it signed by someone authorized to make the commitment.

In addition, many experts recommend that these letters should have a specific structure, including the following three elements:

- **Statement of support** — Use one to three sentences to show enthusiasm and identify the specific project by name.
- **Supporting paragraphs** — Explain how the individual's or site's research, expertise and technical skills will support the applicant. Detail the individual's or site's relevant experience and how it bears on the project, as well as his or her previous track record on similar projects. And if you have worked with them before, describe the project and the results. Finally, explain specific duties to perform, and describe the use of any equipment or other resources.
- **Cordial closing** — The closing's formality will depend on the relationship between the applicant and the person who is supporting them. If the two have a previous productive working relationship, it can be less formal. If that relationship is more limited, the closing should be more formal.

Letters of Support Can Help New Investigators

If you are a young investigator, you can use letters of support from your department chair, collaborator(s) and contractor(s) to fill in any gaps in the capabilities outlined in your Biographical Sketch. The letters can even be from colleagues with whom you have worked. These letters do not fall within the NIH's application page limit, so you can include as many as you feel are necessary.

For standard R01 applications, NIH reviewers will weigh the importance of letters of support based on whether there is a significant gap in your capabilities that must be filled by a collaborator. In these cases, simply naming a consultant

will not be sufficient. You will need a strong, specific letter of support from that individual stating exactly what he will provide to the project and demonstrating enthusiasm for it.

Although technically not required for collaborators who are co-investigators with Biosketches in the proposal, a letter of support may still prove valuable if you have a history of working with the individual.

Also, if you are entering a new field having a letter of support from an established expert in that field is beneficial. For example, if you are a junior investigator examining the impact of Alzheimer's disease on the social interactions of people with the disease in its early stages, getting a clinician with expertise in that disease to write a supporting letter helps to establish your credibility.

Multiple PIs Means Additional Documentation

If your proposal includes multiple Project Directors (PDs)/Principal Investigators (PIs), you will have to complete and upload a separate Biographical Sketch for each of the PDs/PIs. In addition, you will have to create and upload a Multiple PD/PI Leadership Plan.

Direct from NIH: The NIH Application Guides states:

For applications designating multiple PD/PIs, a leadership plan must be included. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the Senior/Key Profile form, even those at organizations other than the applicant organization. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be

delineated for the PD/PIs and other collaborators. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application.

If budget allocation is planned, the distribution of resources to specific parts of the project or the individual PD/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.

What this means:

NIH does not place a page limit on this document, stating only that it should include the following:

A. The rationale for choosing a multiple PD/PI approach rather than having a single PD/PI to lead the proposed research.

B. The governance and organization structure of the leadership team and the research project, including:
  - Communication plans;
  - Process for making decisions regarding scientific direction; and
  - Procedures for resolving conflict.

C. The roles and administrative, technical and scientific responsibilities for the project or program for each of the PDs/PIs and other collaborators.

In addition, if you have planned the budget allocation, your Leadership Plan should detail resource distribution to specific project components or individual PDs/PIs.

NIH offers the following examples of Leadership Plans (http://grants.nih.gov/grants/multi_pi/sample_leadership_plans.pdf), noting that applications should follow any special instructions offered by individual ICOs:

Example 1:

Principal Investigator 1 and Principal Investigator 2 will provide oversight of the entire program and development and implementation of all policies, procedures, and processes. In these roles, PI-1 and PI-2 will be responsible for the implementation of the Scientific Agenda, the Leadership Plan, and the specific aims, and ensure that systems are in place to guarantee institutional compliance with U.S. laws, Department of Health and Human Services and National Institutes of Health policies including human research, data and facilities.

Specifically, PI-1 will oversee aim 1 and be responsible for all social network analysis. PI-2 is responsible for aims 2, 3, and 4 including the implementation of all human subjects research and approvals. PI-1 will serve as contact PI and will assume fiscal and administrative management including maintaining communication among PIs and key personnel through monthly meetings. He will be responsible for communication with NIH and submission of annual reports. The responsibilities of the contact PI will be rotated to PI-2 in even years of the grant award. Publication authorship will be based on the relative scientific contributions of the PIs and key personnel.

Example 2:

Principal Investigator 1 at Institution A will be responsible for the oversight and coordination of project management for aim 1 involving the collection of data from families of transitioning youth with autism. Principal Investigator 2 at Institution B will be responsible for aims 2 and 3 including the further development and testing of a protocol to determine resources available through family social networks. Each PI will be responsible for his own fiscal and research administration.

The PIs will communicate weekly, either by phone, e-mail, or in person, to discuss experimental design, data analysis, and all administrative responsibilities. All PIs will share their respective research results with other PIs, key personnel,

and consultants. They will work together to discuss any changes in the direction of the research projects and the reprogramming of funds, if necessary. A publication policy will be established based on the relative scientific contributions of the PIs and key personnel.

PI-1 will serve as contact PI and be responsible for submission of progress reports to NIH and all communication.

Intellectual Property: The Technology Transfer Offices at Institutions A and B will be responsible for preparing and negotiating an agreement for the conduct of the research, including any intellectual property. An Intellectual Property Committee composed of representatives from each institution that is part of the grant award, will be formed to work together to ensure the intellectual property developed by the PIs is protected according to the policies established in the agreement.

Conflict Resolution: If a potential conflict develops, the PIs shall meet and attempt to resolve the dispute. If they fail to resolve the dispute, the disagreement shall be referred to an arbitration committee consisting of one impartial senior executive from each PI's institution and a third impartial senior executive mutually agreed upon by both PIs. No members of the arbitration committee will be directly involved in the research grant or disagreement.

Change in PI Location: If a PI moves to a new institution, attempts will be made to transfer the relevant portion of the grant to the new institution. In the event that a PI cannot carry out his/her duties, a new PI will be recruited as a replacement at one of the participating institutions.

CONCLUSION

After your Abstract, many reviewers turn to your Biographical Sketch as the next stop in their assessment process. They want to make sure you have the skills, background and general acumen to take on the research you are proposing.

And with each of these sections, you have only very limited space to present the details that support your research, education and overall background to demonstrate early in the application that you have a viable proposal worth funding. You want to grab the reviewers' attention, get them emotionally involved and turn them into champions for your project. ∎

Your Notes:

Chapter 4:
Showing Your Institution's Resources and Commitment

One of the core criteria National Institutes of Health (NIH) reviewers use to score your grant application is the Environment in which you perform the research.

They want to ensure you will have the resources — meaning the institutional support, equipment and physical items — you need to successfully complete your proposed investigation. For social and behavioral scientists, institutional resources usually consists of office space, computer and software necessary to carry out your project, library facilities, specialized lab space for interviews or focus groups (if needed), and the willingness of your department and institution to give you the time you need to do the project. Time is often the most critical element for this kind of research – if you can't get the course releases or limits on university service to do a complex research project, you are not going to succeed. Additionally, they want to know of any unique features of your scientific environment, subject populations or collaborative arrangements that will benefit your project. You will detail these elements in the Facilities and Other Resources and Equipment sections of the application.

The Facilities and Other Resources section is also the place that you show that you have resources in your targeted research community to successfully do your research. This includes partnerships with host institutions like a hospital, park system, clinic, or community based organizations. It also includes partnerships with organizations that can help you find appropriate participants for your research. As such, many social and behavioral science proposals include information on institutions outside of their university or institute that will provide resources for the project.

Where you perform your research has not always been so important. In fact, reviewers note that "environment is one of the review criteria that used to be virtually meaningless. Almost nobody got a bad score for it." As one characterized it, "The only place that a reviewer could find information about [it] was the list of centrifuges and computers, which is really not very helpful."

Obviously, this is no longer the case.

DETAIL YOUR FACILITIES AND OTHER RESOURCES

Direct from NIH: The NIH Application Guide states:

Facilities & Other Resources

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project.

No special form is required but this section must be completed and attached for submissions to NIH and other PHS agencies unless otherwise noted in an FOA. Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

For Early Stage Investigators (ESIs), describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support. See, http://grants.nih.gov/grants/new_investigators/.

If there are multiple performance sites, describe the resources available at each site.

What this means:

As you construct the Facilities and Other Resources section, you should answer the following questions:

1. What facilities will you use? This section should be filled out for both your own institution and that of any co-PIs or key collaborators. Include the following subheadings and describe the capacities (including square footage), pertinent capabilities, relative proximity and extent of availability of each to your project:

   • Office space or research space at the hospitals or community based organizations hosting your research
   • Computer
   • Office
   • Center resources like a specialized center that performs research on your topic, a survey research entity on campus that can collect data, a GIS laboratory, or a Center with major data sets from the U.S. government and other sources
   • Other, such as specialized computer resources like social network software, specialized space to conduct interviews such as interview or focus group rooms with recording or one-way viewing capacity, or the availability of media or conference call facilities to maintain connections with colleagues at other sites.

2. How will the scientific environment in which you perform your research contribute to your success? Include the following sections, and describe how your studies benefit from unique features of the scientific environment or subject populations and useful collaborative arrangement:

- Institutional support—this involves a several kinds of support:
  - Commitment to provide course releases so that the PI and other key staff have time to conduct the research.
  - For projects using students as research assistants, the university may contribute part of the costs for N number of graduate assistants or work study students.
  - For projects involving students in specific classes as researchers, known as service learning courses, commitment to offer those courses when needed by the research project. This may also include a written commitment to run classes even if they do not meet university enrollment minimums. For example, students in a research methods or Medical Sociology or Anthropology course may gather data for the project as their course project.
  - Availability of administrative staff to handle grants administration.

- Physical resources
- Intellectual rapport
- Proximity and relationships with communities or organizations where the research will be conducted. For example, your university has a teaching hospital in a low income neighborhood two miles from the campus where your office is located or the university has a long standing community outreach to a particular neighborhood or set of organizations in the city where it is located. For rural projects, the fact that the university supports the agricultural extension program or trains teachers or social workers who work in rural communities nearby.

3. For early-stage investigators, describe the following:

- Institutional investment in your success — for instance, resources for classes, travel and training
- Collegial support, such as career-enrichment programs, and availability of organized peer groups

- Logistical support — for example, administrative management and oversight and best-practices training, and financial support such as protected time for research with salary support

4. If there are multiple sites where your research will be performed, describe the resources available at each site.

For this section, you should list any distinctive features, which may include the following:

- A unique set of technical capabilities
- Access to a special patient population
- The collaborative nature of interactions between you and your colleagues
- A particular emphasis in a special area, such as the fact that your institution has a Center that specializes in child development funded by NIH, while one partner institution has a specialized clinic on autism in its hospital, and a third partner is a nationally recognized private research firm with a reputation for collecting survey data.

TIP:

For early-stage investigators, reviewers look for evidence of how your institution values your research and its level of commitment to helping you succeed.

This not only informs reviewers how your institution supports your research, but also underscores your qualifications as the best person to perform your proposed research. For early-stage investigators in particular, reviewers look for evidence of how your institution values your research and its level of commitment to helping you succeed.

In addition, first-time applicants often find succeeding with a proposal rather challenging. They frequently need assistance with start-up funds, access to graduate students, or departmental support for travel, training, or career-enrichment programs.

And if you are an early-stage investigator still working at the same institution where you performed your postdoctoral work, NIH reviewers may be skeptical of your application — especially if you are nearly in the same research area and your

PhD advisor or postdoctoral mentor still has active grants. A reviewer likely will wonder if the funds might indirectly benefit the mentor instead of funding you. You must demonstrate that you are independent and that your proposed research is *your* project.

Reviewers may also be skeptical when you are a long-term postdoctoral researcher and your institution offers to make you a research assistant professor — *if* you get a grant. NIH wants to see that your institution has already made you a research assistant professor, not that it is making its commitment to you contingent upon you getting the grant.

Remember that institutional support also addresses your research's feasibility, including your freedom to carry out your research, away from classrooms, advising, committees and other day-to-day duties that compete for your time. Reviewers want to be sure that you will have both time and facilities to tackle the research that you describe.

At the same time, some may believe that NIH chooses reviewers only from "distinguished" institutions, which may create a sense of bias. But the average study section likely offers a geographically and scientifically diverse panel, and many reviewers work at or certainly appreciate the constraints of working at institutions that might lack unlimited resources.

Resources Support Independence

There is no limitation regarding this section's length as long the information you provide specifically relates to your available facilities and resources.

As you write this section, there are some key elements that you should include – if they are applicable to your proposal:

REMEMBER:

Institutional support addresses your research's feasibility, including your freedom to carry out your research, away from classrooms, advising, committees and other day-to-day duties that compete for your time.

- Support your "intellectual rapport" section by explaining any collaborations with same-institutionbased colleagues who impact your proposed research.

- Identify any outreach activities of the institution, centers, clinical or applied programs attached to institution. For example, a nationally recognized applied program in aging or a NIH funded Center on obesity. This would also include institution sponsored services to the community like teaching hospitals, a resource center for developmental disabilities, or a community outreach clinic. Mentioning these centers, programs or facilities shows that you have both intellectual resources that will help you complete your work and already established programs that can help you find participants for your project. If these programs or facilities are well known, they can also add to the prestige of your institution.

- Highlight the unique population of your locality, noting such things as underserved groups, high incidences of specific diseases or conditions, rural/ urban setting, etc.

- Stress your access to pertinent resources based upon geography — for example, proximity to veterans' centers, public health facilities, children's hospitals and states' departments of health, among others.

- Underscore proof of institutional support such as mentoring availability, university-based grants, institutional clinical research centers and library support.

- Make sure the Facilities and Other Resources matches your proposal's budget request section.

- Take advantage of the correct adjectives when describing your resources — "specially-constructed modules," "state-of-the-art laboratory," "cutting-edge clinical operations," "dynamic imaging" and "centralized data collection," to get you started.

STRATEGY:

Support your "intellectual rapport" section by explaining any collaborations with same-institution based colleagues who impact your proposed research.

One option as you construct this application document is to use subheadings that reflect NIH's requirements. Although the agency does not require a special form for this document, you might consider the following outline based upon NIH-requested information and suggested items from several university grant administration offices:

Facilities and Other Resources

XXX University/Institution

In this section, outline the general scientific environment in which you will conduct your research and how it will contribute to your proposal's successful outcomes.

Research Population: If you have target populations nearby, include this section and use it to note ways in which your research will benefit from the subject populations in your area.

Research Facilities: Here, indicate how your institution's resources will support your proposed research. Denote any specific elements that will be available, such as social network software and staff who can do analysis for you if you are doing network analysis, and the extent to which they will be available. Also, mention any additional institution-specific facilities that might impact your proposal — for instance, associated children's healthcare centers, public clinics, veterans' hospitals, etc. And if there are multiple research sites, describe the resources available at each.

Collaborative Arrangements/Intellectual Rapport: Detail any collaborative relationships with your institutional colleagues — such as mentors and other investigators, among others.

Departmental Resources: In addition to institutional resources, be sure to indicate any within your department or division that may benefit your research.

University Centers or Specialized Programs: These range from Centers studying particular topics that could provide administrative support and intellectual support for your project to data labs that have government statistics or national data sets or GIS labs.

Institutional Support: As stated earlier, indicating your institution's support for you and your research is key for reviewers, and you should use this section for this purpose. This can include available mentors, administrative support and grant-writing education.

Institutional Commitment to the Project: Course releases, graduate assistants or student interns, confirmation of willingness to offer service learning courses.

Office and Research Project Space: This should include office space not only for you, but your key staff and student researchers. It may also include space for secure storage of data. You may need to list office space both at your home institution and at research sites. Include location(s), number of office(s) and square footage.

Computer: Here, you should indicate the computers, databases, servers and other data storage/computing equipment available for your project.

Resources at Host Sites: This would include the physical facilities to carry out your project and the availability of supportive staff to facilitate your work. If your project will use organization administrative data sets, information confirming that the facility has the record keeping capacity to provide the data you need. If the organization is identifying potential research participants, discussion of the populations that use the center and their experience in hosting research projects in the past.

Clinical: Use this section to note clinical facilities that are available at your institution.

If you are an early-stage investigator, you should include all of the above, and you can add the following section for the Facilities and Other Resources document:

Early-Stage Investigator

Resources for Continuing Education: In this section, note any institutional resources for classes and/or training and career enrichment programs.

Institutional Support: You can break this section into the following two areas:

Mentorship: Detail how your institution/department fosters your research efforts through a mentorship program.

Collaboration: If your institution offers organized peer groups, you can note that here.

Logistical Support: Indicate any assistance with administrative management and oversight, as well as training offered regarding best lab management practices and other topics.

Financial Support: If your institution ensures protected time for research with salary support, startup funds or institution-sponsored grants, you should detail that in this section.

Here is an example of a Facilities and Other Resources section from a successful grant application.

From NIA sponsored project 1R01AG041955-01A1 Understanding How Personal Networks Change. Names of individuals and institutions have been redacted.

 FACILITIES AND RESOURCES

Laboratory: NONE
Clinical: NONE
Animal: NONE

UC A

   Office: Dr. PI has an office on campus located in the. Department of Sociology, and is also an affiliate of the A Population Center and the Center for the Economics and Demography of Aging. As such, Dr. PI will have access to the Sociology Department's and the two Centers' support staff ,meeting rooms, high volume copying machines, scanners, fax machines, and other office equipment/supplies/ services as needed. The other personnel on the project, including the project director, postdoctoral fellow, and the graduate student researchers, will be provided offices through CEDA or the A Population Center.

   Computer: Computing facilities are provided by the Department of Sociology (which has access to the Social Sciences Computing Laboratory) A Population Center and the Department of Demography.

   The Demography Lab is used for demanding statistical computing, and includes all up-to-date statistical software (e.g., STATA, R, SAS and others). The technical staff (Drs. B and C) are knowledgeable both about technical computing issues as well as substantive demographic and statistical issues, and the lab's design stresses usability of resources by persons on the same project, and enhanced remote, secure access.

All computer centers have a full set of software for statistical analyses (SAS, Stata, SPSS, R), dataset management and other standard resources.

Other: UC A Resources:

UC A is renowned worldwide for the distinction of its faculty and students, the scope of its research and publications, and the quality of its libraries. Its academic departments consistently rank among the top five in the country. The faculty, renowned for both teaching and scholarship, includes eight Nobel Laureates and 30 MacArthur Fellows. In addition, the research, teaching and service conducted at the UC A is highly regarded and has a broad reach throughout the San Francisco Bay Area, an important factor in gaining trust in the research.

UC Data: Provides data archival resources. Data archived here may also be simultaneously archived at ICPSR. UC Data supports the social science data needs of UC A researchers, and provides access to a broad range of computerized social science data to faculty, staff, and students at UC A. Through its director, UC Data helps researchers understand the content and context of social science data, including geography, weighting, complex designs, and missing data. It also provides and supports careful and thorough analysis of special issues, problems, programs and populations. UC Data is also part of the U.S. Census Bureau's State Data Center Network (SDB/BIDC), and serves as the regional center for distributing U.S. Census data in California. It will support us when we enter the phase of resource sharing of these data, including but not limited to creating a data plan, working with CENTER and other aspects of the data management.

A Population Center. The A Population Center provides research support for population researchers at UC A. It consists of nearly 60 active researchers among its faculty, researchers and postdoctoral scholars. Office space for visiting researchers Is provided and training is provided to faculty through graduate students on issues around methods and grants. Seminars and colloquia are provided year-round to present research conducted by faculty here and elsewhere. Small groups around research themes are supported (one such group on social networks supported the development of this grant). In addition, it can disseminate

information about the research, as well as provide a channel for seeking input and resources. It is supported by an NICHD grant R21 XXXXXXX.

Center for the Economics and Demography of Aging: supported by NIA P30XXXXX, is a response to the growing demand from government agencies, Congress, and academic researchers for timely, accessible, and practical information as well as basic research. As one of fourteen centers established by the National Institute on Aging, the A Center forms part of the national Infrastructure for developing the relatively new field of the economics and demography of aging. At the core of CENTER is a group of outstanding mathematical and statistical demographers who apply their skills to a variety of research areas, including biodemography, demographic modeling and forecasting, and intergenerational transfers including fiscal accounting. This central core is enriched by other themes, notably psychological and behavioral economics with applications to survey design and health economics. Having this resource available to this project is of critical importance. This proposed study emerged following a pilot grant co-funded by CENTER and A Center.

School of Public Health: The School of Public Health at the University of California, A, will provide administrative oversight for the grant and its research activities. Since its founding, the School of Public Health has become one of the world's preeminent centers dedicated to the promotion and protection of the health of human populations and is noted for the excellence of its programs in teaching, research, and service activities. These programs, grounded in an understanding of biological and social science theories and mechanisms, are integrated through a focus on communities that reach from the neighborhoods surrounding the A campus to settings around the world.

Libraries: The University of California, A is home to the top public library in the United States. These include the Public Health Library in University Hall, which has a collection of more than 102,525 volumes, receives more than 1,100 print serial titles, and along with the entire campus community, has access to more than 85,000 online serial titles. The collection, in itself rich in all aspects of public

health, is enhanced by the holdings of other subject specialty libraries such as the Bioscience & Natural Resources Library, the Social Welfare Library, the Chemistry Library, and the Long Business & Economics Library. Public use computers in the library provide access to the library catalogs, to the University of California and A licensed resources, and to other resources on the Internet, most of which can also be accessed remotely.

II. DATA COLLECTION

RESEARCH COMPANY C CORPORATION

RESEARCH COMPANY C 's capabilities are well-known. We enlisted RESEARCH COMPANY C in the data collection effort because of the proven capability in web-based data collection around network items as evidenced in their SHARE study using the MMIC® software described below. We will be working with [co-PI B's] group to provide this expertise as well as sample weights, arranging for compatibility between the web and face-to-face data collection, and transfer of data and survey materials to Research firm B (see below).

Office: For 60 years, decision makers in the public and private sectors have turned to the RESEARCH COMPANY C Corporation for objective analysis and effective solutions that address the challenges facing the nation and the world. These challenges include such critical social and economic issues as education, poverty, crime, and the environment, as well as national security issues. Today, RESEARCH COMPANY C researchers and analysts continue to be on the cutting edge of their fields, working with decision makers in both the public and private sectors to find solutions to today's difficult, sensitive, and important problems. Through its dedication to high-quality and objective research and analysis and with sophisticated analytical tools developed over many years, RESEARCH COMPANY C is engaged with its clients to create knowledge, insight, information, options, and solutions that will be both effective and enduring.

RESEARCH COMPANY C currently employs more than 730 research professionals; 85 percent hold advanced degrees, most commonly the doctorate.

In addition, RESEARCH COMPANY C maintains consultant contracts with over 500 researchers and scholars, who can be called upon if a particular expertise is not available in-house. RESEARCH COMPANY C has three principal locations: Santa Monica, California; Arlington, Virginia; and Pittsburgh, Pennsylvania. Other RESEARCH COMPANY C offices include RESEARCH COMPANY C Europe in the United Kingdom; the RESEARCH COMPANY C -Qatar Policy Institute in Doha; and several smaller sites.

RESEARCH COMPANY C's information infrastructure facilitates work across multiple RESEARCH COMPANY C locations. Computer and email systems link the offices and provide immediate access to data. Other communication tools include interactive video teleconferencing facilities and an overnight Federal Express pouch. Research teams at multiple sites can easily collaborate electronically. Small groups can quickly set up impromptu electronic meetings from their personal computers to collaborate on documents and work through analytical results. Several conference rooms are outfitted with fixed computers, projectors, and wireless keyboards to accommodate larger electronic meetings and to broadcast remote seminars.

To provide the varied expertise required to fully address major issues, RESEARCH COMPANY C has developed a professional staff representing a wide range of disciplines. RESEARCH COMPANY C's areas of expertise include child policy, civil and criminal justice, education, environment and energy, health and health care, Infrastructure and transportation, international affairs, national security, population and aging, public safety, science and technology, and terrorism and homeland security.

Research Support: RESEARCH COMPANY C provides strong research support services, including highly sophisticated computing software and hardware systems, an extensive data collection facility, a state-of-the-art publications department, and financial systems for tracking projects, and professional advisory groups that contribute statistical, survey, and communications support to projects. We highlight some of these support services below.

Statistics Group: The Statistics Group makes many different kinds of statistical expertise readily available to all members of the research staff. The group provides consulting in such areas as data analysis, theoretical and applied statistics, probability modeling, and statistical computing. In addition to this advisory role, the group uses RESEARCH COMPANY C funds to pursue methodological research that grows out of RESEARCH COMPANY C research projects. In its research role, the group maintains and pushes the state of the art in statistical modeling.

Computing Operations and Services:

RESEARCH COMPANY C's computing systems include over 2,000 microcomputers running Windows and Macintosh operating systems, and over 100 workstations running Sun Solaris or Linux. All are connected in an internal network with global reach, allowing e-mail, file sharing, and access to RESEARCH COMPANY C's intranet, as well as to the Internet. Exchange servers support e-mail using MAPI, IMAP, and POP clients. Dialup access to RESEARCH COMPANY C's network is available worldwide via lnfonet's DialXpress access points.

Other forms of collaboration available.to RESEARCH COMPANY C staff include data conferencing using the applications NetMeeting (Windows-based) and Timbuktu (Windows and Macintosh), which are installed on all RESEARCH COMPANY C microcomputers; videoconferencing via facilities in each RESEARCH COMPANY C site; and Web conferencing via a dedicated RESEARCH COMPANY C WebEx site.

RESEARCH COMPANY C's computing support staff of over 140 provide a full complement of research programming, system administration, Help line, and troubleshooting support services.

Data Collection:

Survey Research Group: The Survey Research Group Includes a full-time, 25-person staff working in. Santa Monica, California, and Washington, D.C.

Survey directors and coordinators provide start-to-finish continuity for projects, with a single staff member taking responsibility for a project from initial design through delivery of a final product. The survey operations staff collaborates closely with the survey directors and coordinators to provide a project's operations needs- instrument layout, document production, data collection, coding, and data reduction, as well as cost control. SRG has a computerized telephone interviewing center with the capability for remote monitoring by clients, as well as facilities for mail surveys, packet preparation, coding, and data entry. It also staffs and carries out personal interviewing projects around the country and abroad.

Survey Support: MMIC™ RESEARCH COMPANY C Labor and Population has led the development of a comprehensive information system, MMIC™ (Multimode Interviewing Capability), building on work by CentERdata in The Netherlands. MMIC™ integrates various traditional modes of collecting interview data, including telephone interviewing, self-administered surveys, and personal interviewing. MMIC™ is used to manage the whole data collection process from questionnaire design, sample management, and fieldwork monitoring to final dataset production.

MMIC™ is designed to overcome many of the limitations inherent in existing survey processing suites, particularly for the kind of large-scale CATI/CAPI questionnaires that are currently being fielded. In addition, substantially reduced development times result from a full-featured set of programming tools and from the greatly expanded set of debugging features available in MMIC™. As a consequence, greater accuracy and responsiveness to the needs of the researchers can be obtained and programming overhead can be reduced.

MMIC™ integrates the layout of the questionnaire with the metadata and exports to a uniform central (meta) database. Data entry programs and a sample management system for all modes are included as well as support for survey control utilities. Furthermore, there are advanced plans to include tools in MMIC™ for metadata viewing, generating codebooks and exporting well-documented files

of the survey responses that are ready to load into STATA and other statistical analysis software, or spreadsheet/database programs.

RESEARCH FIRM B

Research firm B, is a division of the XXX Group, a research and consulting firm. It was founded in 1984 by two PhD sociologists to provide a high level of data collection expertise to a broad range of clients: academic, policy, government and corporate. Services include statistical analysis, economic modeling, field studies and data collection that can serve as the basis for policy analysis, as well as business and litigation strategy. They are one of the few firms in the Bay Area that does face-to-face and other forms of personal interviewing, and they specialize in hard-to-reach populations, including surveys in Spanish and Chinese. Two exemplary studies are for public utilities in developing policy for rates and other practices that encourage energy efficiency, as described briefly here:

Understanding the Impact of Lifestyles and Perceptions on DR Behavior
 XXX worked with Pacific Gas & Electric (PG&E), California Public Utilities Commission, and California Energy Commission to study how households use energy and how they decide when to use it. They called customers who have been mailed a letter and screened for households that fit the profile we sought, and obtained a verbal agreement for participation. They assured customers that data would be handled securely and entered data using serial numbers rather than personal identifying information. They accommodated customers' availability and scheduled licensed technicians to drive to residences, where customers had enough trust to even allow them into their bedrooms, to install devices which record energy use of electric appliances.

Technicians did energy audits and spoke with customers about their energy usage. Customers received $100 as a VISA gift card or a check. Over the course of the study, they conducted 3 telephone interviews, and later drove back to residences for in-person interviews, after which, customers received another $100.. Customers signed an acknowledgement that they received the incentive, and they promptly

handled emails or phone calls when customers claimed to have not received their incentive.

PG&E In-home survey and Energy Audits

In September 2012, they will be assisting Pacific Gas & Electric (PG&E) with conducting in-home surveys and energy audits. During the visit, we will be administering a questionnaire and checking energy efficiency measures. The customers to be visited would have received a home energy usage report from PG&E. They will be sent a pre-announcement letter and encouraged to call in to schedule the appointments. There will also be outbound calling to those who did not call in. A $50 incentive will be disbursed at the end of the visit.

Office: Data collection will be carried out by Research firm B located at [address], San Francisco, CA. In business since 1984, Research firm B, a certified Small Business Enterprise (#26674) and a certified Disabled Veteran Business Enterprise (also #26674). XXX

Computer assisted telephone (CATI) interviewing is conducted out of this office at its state-of-the-art call center. This new call center accommodates 20 stations. XXX has extensive experience in health research, research with children and other specialized populations. The XXX office in San Francisco is conveniently located for ease of access for consultations and. meetings during the data collection period1 which is highly advantageous during this longitudinal study.

Computer: Research firm B uses the Sawtooth WinCATI data collection software for CATI studies as well as for those projects that integrate both telephone and web-based data collection. WinCATl/Sensus mode allows for the kind of mode effect test that will be central to this study.

Data Collection: Interviewing quality control procedures are rigorous. For a project of this nature, the interviewers will go through at least 40 hours of training.

In addition, each interviewer will undergo an additional 2-3 hours of training for each step of the project. The interviewers will be presentable, professional and respectable; they will also pass a background check (including felony, misdemeanor and DUI) and all interviewers and recruiters dispatched are checked against the National Registry of Sex Offenders as well. They will be provided with a uniform (light gray polo shirt with a logo), a badge with a photo of the interviewer with an official logo (XXX or UC A's). For this study all interviewers will have at least a Bachelor's degree or at least 5 years of social/public research (not simple commercial research). Supervisors follow up at least 40% of each interviewer's respondents within 24 hours.

Respondents are given a prepaid comment card when they receive incentive checks.

LIST YOUR AVAILABLE EQUIPMENT

In addition to your institution's resources, your application also must list the equipment available for your research. This may be relevant to social and behavioral science applications that include watching how people respond to specialized environments like studies of ways that people interact with machines designed to improve their mobility. Projects that involve analyzing video and videotaping in a specialized room may need to show that they have rooms with up--to-date equipment to perform this kind of research. However, the majority of social and behavioral science projects will not need specialized equipment for their research. NIH is not interested in inexpensive, regularly available equipment like laptops or tape recorders. These types of items should not be listed in an equipment section.

Direct from NIH: The NIH Application Guide states:

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities.

What this means:

The list includes "major items of equipment." And be sure to indicate their locations and capabilities. NIH defines "equipment" as "an article of tangible, nonexpendable, personal property that has a useful life of more than one year and an acquisition cost of $5,000 or more, or the capitalization threshold established by the organization, whichever is less."

If your institution receives little NIH funding, however, the agency maintains that you should list even basic items.

Here is an example of how many social and behavioral science proposals respond to the equipment list requirement as part of a facilities statement.

From NIMH sponsored grant 1R01MH099190-01A1 FAMILY OUTCOMES IN AUTISM SPECTRUM DISORDERS. Institution and individual names have been redacted.

Facilities & Other Resources

The Center A at the University of STATE (www.CenterA.edu) is an internationally renowned center dedicated to research, service, outreach, and training to benefit people with developmental disabilities and their families. The Center A is a 210,016 square-foot complex that was originally opened in 1973. It is one of nine centers in the nation that houses both an Intellectual and Developmental Disabilities Research Center (designed by the National Institute of Child Health and Human Development) and a University Center for Excellence in Developmental Disabilities Research, Education, and Service (designed by the Administration on Developmental Disabilities). The Center A is the largest interdisciplinary research center in the U's Graduate School. The Center A clinics and support programs serve more than 2,500 people a year. The Center's $40 million annual budget originates from a combination of federal, state, and private sources. A description of the resources most relevant to this application is provided below.

The Center A receives support from the Eunice Kennedy Shriver Intellectual and Developmental Disabilities Branch of the National Institute of Child Health and Development (NICHD) for the State Intellectual and Developmental Disabilities Research Center (MRDDRC). The Center grant (P30) supports an administrative core and the research infrastructure of the Center A through Center A Core Services, which provide essential, high-quality services to biomedical, behavioral and social science research projects.

Laboratory:

The proposed project will have access to a lab located on the fifth floor of the Center A. This lab will be used to conduct phone calls and organize materials. It

is also a secure room where data can be stored in locked file cabinets. This lab contains 2 computers and ample space for research staff to conduct the daily work on the proposed research.

An assessment room located on the first floor of the Center A will be used to conduct the study. This room will provide a naturalistic home-like setting for unobtrusive videotaping of the couple problem-solving task. Specifically, the room is decorated to look like a modern-day living room, including a couch, table, chairs, and bookshelves. Two remote-controlled digital cameras are attached to different walls of the room. When a couple is seated facing each other at the table or on the couch, the cameras allow split screen images of both individuals' faces. The room also has ceiling microphones. A control room is located adjacent to the interaction room for camera control, taping, editing, dubbing and coding of videotape.

Computing:

The proposed project will have access to the Center A Computing Service. This Service provides support for computing and data communications, including the design, installation, maintenance, and management of the digital communications infrastructure of the Center (i.e., operation and back-up of servers for email, internet, and user files, the design and maintenance of PC systems, and assistance with programs and database design and usage).

The Center A secured network is managed by the Center's Computing Service. The network consists of over 600 workstations of all varieties (Windows, Macintosh, linux, and unix) along with 150 printers, scanners, and specialized research equipment attached via switched Ethernet connections distributed among 14 access points. The access points are each tied with a 1 GB connection to a redundant central switch/router and also routed to the campus network (10 GB backbone) and on to the internet and internet2. The Center has wireless coverage such that investigators and staff can access the internet in a secure manner from mobile devices. Centralized network services are provided by a cluster of enterprise class HP Alphaservers (ES Series) operating in a load-balanced, shared everything, fault resilient environment. Servers have two paths to a fully redundant, switched

fiber channel fabric (2GB/sec) that comprises a storage area network (SAN). This provides the servers with very high speed access to a large capacity (5TB), virtualized storage array with no single point of failure. The SAN fabric is extended by interswitch links to application servers and a high capacity robotic tape library. The robotic tape is automated by enterprise level commercial software for "lights out" operations during off hours providing a daily backup schedule along with off site tape rotation that protects data against loss. All network equipment is powered by uninterruptible power supplies.

Office Space:

Offices are provided for [PI and key staff] and graduate and student hourly project staff. Offices are equipped with PCs connected to the Center A's commuting network. Additional office space in the Center A will be made available on an as-needed basis. Staff person D's office is located in the M building, a nearby university facility.

Equipment

None.

SHARING PLANS ADDRESS SPECIFIC RESEARCH RESOURCES

NIH wants to know you will appropriately share any resources developed through its grants and requires you to complete three plans as part of your application in certain circumstances:

1. Data-Sharing Plan
2. Sharing Model Organisms
3. Genome-Wide Association Studies (GWAS)

Usually, most social and behavioral science applications will only need the data sharing plan. In many cases, researchers will not share their data because of privacy concerns. However, some projects will create de-identified data sets that other researchers can use for their own work. These kinds of data sets should be described in a data sharing plan.

Direct from NIH: The NIH Application Guide states:

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Supplemental Instructions Part III, 1.5 Sharing Research Resources.

1. Data Sharing Plan: Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&A) in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Specific Funding Opportunity Announcements may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss

their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.

What this means:

These are separate documents that you upload as part of your application, but they do not count toward the application page limit.

Keep in mind that reviewers will comment on your resource sharing plans. If you argue that your resources should not be shared — which is an option in specific situations — they will scrutinize any rationale you propose as well.

Data-Sharing Plan

If your grant application requests $500,000 or more in direct costs in any year of the proposed research, NIH expects you to include a data-sharing plan with your proposal. Remember also that if your application is a response to a particular Funding Opportunity Announcement, that announcement might require you to submit this plan regardless of the funding level.

The data-sharing plan should consist of a brief, one-paragraph description regarding how you will share your final research data. Alternatively, if you feel that data-sharing is not possible, you should use this plan to explain why.

What to Include

The exact content of your data-sharing plan will depend on the data you collect and how you plan to share it. For instance, your data-sharing plan might simply describe the following:

REMEMBER:

If you argue that your resources should not be shared — which is an option in specific situations — reviewers will scrutinize any rationale you propose as well.

- Expected data-sharing schedule,

- Final dataset's format,

- Documentation to be provided,

- Whether you will provide any analytic tools,

- If you will require a data sharing agreement, including a brief description of the agreement, and

- Mode of data sharing.

Consider the following example from NIH:

This application requests support to collect public-use data from a survey of more than 22,000 Americans over the age of 50 every 2 years. Data products from this study will be made available without cost to researchers and analysts.

User registration is required in order to access or download files. As part of the registration process, users must agree to the conditions of use governing access to the public release data, including restrictions against attempting to identify study participants, destruction of the data after analyses are completed, reporting responsibilities, restrictions on redistribution of the data to third parties, and proper acknowledgement of the data resource. Registered users will receive user support, as well as information related to errors in the data, future releases, workshops, and publication lists. The information provided to users will not be used for commercial purposes, and will not be redistributed to third parties.

Some data-sharing plans, however, may be more elaborate.

For instance, here is an example from an actual grant application from the National Institute of Allergy and Infectious Diseases (NIAID) — Note: Redacted material is indicated by brackets ([]):

Sharing of data generated by this project is an essential part of our proposed activities and will be carried out in several different ways. We would wish to make our results available both to the community of scientists interested in [this

disease] and the biology of [its causative agent] to avoid unintentional duplication of research. Conversely, we would welcome collaboration with others who could make use of the vaccine assessment protocols developed in [the project].

Our plan includes the following:

Presentations at national scientific meetings. From the projects, it is expected that approximately four presentations at national meetings would be appropriate. There is an annual [Disease] Study Group meeting, of which the PI is secretary. This one-day meeting of interested persons presents new information on a variety of topics related to [the disease]. It is expected that the investigators from this [project] will be active participants of this focused group.

Annual lectureship. A lectureship has brought to the University distinguished scientists and clinicians whose areas of expertise were relevant to those interested in [the disease]. Lecturers have been [list of names]. Visiting lecturers will be scheduled to interact with the investigators of the project as appropriate with their specific areas of expertise which will provide an opportunity for members to present their work to the visitor.

Newsletter. The [disease interest group] publishes a newsletter which currently has a circulation of [number]. The newsletter's intent is to disseminate new information regarding [the disease]. The activities and discoveries of [the project] will be allocated 20% of the newsletter's coverage.

Web site of the Interest Group. The [interest group] currently maintains a Web site where information [about the disease] is posted. Summaries of the scientific presentation from the [quarterly project] meetings will be posted on this Web site, written primarily for a general audience. [Link to Web site.]

Annual [Disease] Awareness week. Beginning this fall during the week of [date], the [interest group] will be sponsoring a [Disease] Awareness week. As part of that program, there will be a research poster display with discussions. In future

years, [the project investigators] will be active participants in this program.

SAGE Library Data. [This project] will generate data from several SAGE libraries. It is our explicit intention that these data will be placed in a readily accessible public database. All efforts will be made to rapidly release data through publication of results as quickly as it is possible to analyze the experiments. Data used in publications will be released in a timely manner. SAGE data will be made accessible through a public site that allows querying as has been set up for a similar project. This site can be accessed at [link to Web site].

Alternatively, if you need to justify why you will not share data or wish to restrict it, NIH offers the following examples:

Example 1

The proposed research will include data from approximately 500 subjects being screened for three bacterial sexually transmitted diseases (STDs) at an inner city STD clinic. The final dataset will include self-reported demographic and behavioral data from interviews with the subjects and laboratory data from urine specimens provided. Because the STDs being studied are reportable diseases, we will be collecting identifying information. Even though the final dataset will be stripped of identifiers prior to release for sharing, we believe that there remains the possibility of deductive disclosure of subjects with unusual characteristics. Thus, we will make the data and associated documentation available to users only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are complete.

Further, if you submit a data-sharing plan, NIH expects you to enact that plan. If you fail to comply — depending on the severity and duration of the noncompliance — the agency can act to protect its interests. For example, NIH may make data sharing an explicit term and condition of any subsequent awards you receive.

The NIH also offers the following as a template example plan for addressing key elements for a data sharing plan under NIH extramural support:

Example Data Sharing Plan for FOA-XX-XXXX

What data that will be shared:

I will share phenotypic data associated with the collected samples by depositing these data at _____ which is an NIH-funded repository. Genotype data will be shared by depositing these data at _____. Additional data documentation and de-identified data will be deposited for sharing along with phenotypic data, which includes demographics, family history of XXXXXX disease, and diagnosis, consistent with applicable laws and regulations. I will comply with the NIH GWAS Policy and the funding IC's existing policies on sharing data on XXXXXX disease genetics to include secondary analysis of data resulting from a genome wide association study through the repository. Meta-analysis data and associated phenotypic data, along with data content, format, and organization, will be available at _____. Submitted data will confirm with relevant data and terminology standards.

Who will have access to the data:

I agree that data will be deposited and made available through _____ which is an NIH-funded repository, and that these data will be shared with investigators working under an institution with a Federal Wide Assurance (FWA) and could be used for secondary study purposes such as finding genes that contribute to process of XXXXXX. I agree that the names and Institutions of persons either given or denied access to the data, and the bases for such decisions, will be summarized in the annual progress report. Meta-analysis data and associated phenotypic data, along with data content, format, and organization, will be made available to investigators through _____.

Where will the data be available:

I agree to deposit and maintain the phenotypic data, and secondary analysis of data (if any) at _____, which is an NIH-funded repository and that the repository has data access policies and procedures consistent with NIH data sharing policies.

When will the data be shared:

I agree to deposit genetic outcome data into _____ repository as soon as possible but no later than within one year of the completion of the funded project period for the parent award or upon acceptance of the data for publication, or public disclosure of a submitted patent application, whichever is earlier.

How will researchers locate and access the data:

I agree that I will identify where the data will be available and how to access the data in any publications and presentations that I author or co-author about these data, as well as acknowledge the repository and funding source in any publications and presentations. As I will be using _____, which is an NIH-funded repository, this repository has policies and procedures in place that will provide data access to qualified researchers, fully consistent with NIH data sharing policies and applicable laws and regulations.

Data sharing agreements for social and behavioral science projects cover similar elements, but usually involve creating a deidentified data set including results of a survey or a survey combined with other data. Like a biomedical repository, the data set is usually managed either through a website affiliated with the project, a center that hosts it, or a larger data repository managed by the university or a consortium of universities. For example, the Understanding Social Networks study example above includes a data sharing plan stored at a university wide data sharing repository. In general, social and behavioral science data sharing plans should include answers to the following questions:

1. What kinds of data will be made available to the public?

2. How will the privacy and confidentiality of the study subjects be protected in this data set?

3. Where will the data set be stored?

4. Who will have access to it?

5. Will user's need to ask permission to use the data, sign a sharing agreement, or otherwise apply to use the data?

CONCLUSION

Environment is one of the core criteria that NIH reviewers will use to assess your grant application. Therefore, you cannot afford to give your Facilities and Other Resources section short shrift. And simply providing a list of lab equipment and supplies that you will have access to will not suffice as well.

You will have to demonstrate that your institution is behind you and your research. And this is particularly true for early-stage investigators.

Similarly, NIH requires you to indicate how you will share your data. This is an effort by the agency to enhance the value of your research and promote additional investigations in your field. The plans you propose for sharing these materials — or refusing to do so — will be part of the materials reviewers will scrutinize and use to assess your application. ■

Chapter 5:
Proving Your Research Topic's Significance

"Good scholarship is not about science, it's about an important, compelling idea that gets taken seriously and fairly. It's about [writing your proposal in such a way that peer reviewers can] recognize good scholarship."

This quote, from an interview with a senior social scientist who has written several successful R01s and chaired peer review panels, explains the key to writing a successful R01 application. The goal in writing a successful proposal is not to prove that you know the literature better than others in your field, have developed a clever scientific technique, or to demonstrate that you can perform scientific research successfully and publish it. Instead, you need to show that you have an actionable compelling idea that will make a difference to public health or the course of a specific disease and that you have thought of the right methods and research questions to realize that goal. The core of the proposal is the research plan. This chapter focuses on aims, goals, and methods sections of the application.

Your goal in developing your proposal is to clearly and concisely tell the story of how your project will achieve its goals and Specific Aims. Remember, as one program officer stated, "Pretend you are writing for your dentist." You only have 13 pages to present your idea and explain why your methods will achieve the aims you set out. You also need to hammer home in every section of the application that these Specific Aims will be innovative and have a concrete impact on public health or a specific health problem. The peer review panels that will review your application consist of people who focus on a particular problem, and intentionally not all of them will be experts in your methods. In fact, most peer review panels include clinicians, epidemiologists, or other practitioners. The three people who review your proposal (possibly the only ones who have actually read the whole thing), may also include a practitioner or someone from another field. Your writing should presume that reviewers do not know your field, meaning that you must use plain language and explain your methods in ways that those not trained in them can understand.

Senior scientists and program officers stress that you are writing for several audiences. The primary ones are the peer review committee, your program officer, and the advisory council at the Institute or Center that will make final decisions on what proposals are funded. In each case, you will likely be explaining your research methods, research questions and goals to people who have a general understanding of your methods, but are looking for its broader impact on the scientific field and health.

While all proposals need to be written clearly and concisely, this is more difficult for social and behavioral scientists because of the range of methods and the fact that biomedical scientists and practitioners may be less familiar with them. This chapter will discuss ways to present your significance, aims and methods within the 13 page limit, 1 to describe the Specific Aims and 12 for the rest of the research strategy section. It also includes a brief discussion of possible methods for social science proposals.

Probably the most important parts of your National Institutes of Health (NIH) R01 application are those in which you describe your proposed research. Specifically, these are the Specific Aims and Research Strategy sections. They address your project's Significance, Innovation and Approach, which are three of the five core grant criteria that reviewers use to score your application.

The most successful proposals interweave significance, aims and goals throughout the proposal narrative. Senior researchers and program officers emphasize that you need to carefully craft your goals and aims, and show throughout the proposal why those goals are important through reference to what has been done in the field. Your aims should be linked closely to your methods, showing how your methods will achieve the Specific Aims and ultimately meet your goals. In fact, many proposals mix significance, aims and methods together by discussing the significance and methods for each aim separately. Examples, shown later in this chapter, will illustrate this strategy. Senior researchers emphasize that you need to use the exact same words to describe your aims and goals throughout the proposal, as changing the way you describe them can be viewed as unclear writing or not clear goals/aims by reviewers.

TIP:

Many proposals mix significance, aims and methods together by discussing the significance and methods for each aim separately. You need to use the exact same words to describe your aims and goals throughout the proposal, as changing the way you describe them can be viewed as unclear writing or not clear goals/aims by reviewers.

At the same time, these sections will heavily influence your application's Overall Impact score. Unfortunately, there is no template for incorporating overall impact into your application, and there is no section called "Overall Impact" — or even an incentive to simply add a paragraph labeled as such. Instead, the NIH Office of Extramural Research has stated that you should describe "impact" clearly in the words you feel are relevant to your project.

Consequently, we will examine how you can use the Specific Aims and Research Strategy to perform double-duty:

1. Fulfill the Significance, Innovation and Approach criteria
2. Support the Overall Impact of your research

As you address each of these sections, note that NIH limits your Specific Aims to no longer than one page, and the Research Strategy cannot exceed 12 pages for an R01 application.

Language Is Important

Also keep in mind that although terms like "aims," "goals," and "objectives" may seem interchangeable, they have separate meanings within your application.

- **Goals** are strategic and high-level. For instance, "the goal of this project is to examine the within-family associations between the autism symptoms and behavior problems of children with ASDs and marital adjustment as these processes unfold in naturalistic contexts and across three years." (From NIMH sponsored grant 1R01MH099190-01A1 FAMILY OUTCOMES IN AUTISM SPECTRUM DISORDERS)

- **Objectives** often are a restatement of your major research question in a way that it can be proven or disproven. Objectives are less often used in certain kinds of

social science proposals. For example, for the same project, an objective might be "to understand how the symptoms and behaviors of children with ASD create challenges for their parents' relationship."

- **Aims** are the outlines of your tactics or tasks to be performed. For instance, for the same study, specific aims are: "1) Compare the self-reported and observed marital adjustment of couples of children with ASDs as compared to couples who have children without disabilities; 2) Test the within-family day-to-day temporal effects of child symptoms and behavior problems on couple interactions."

Or think of it using this analogy:

- Goals are the view from 30,000 feet
- Objectives are the view from 10,000 feet
- Specific Aims are the view from 1,000 feet

Goals and aims vary widely for social and behavioral science proposals because there are such a broad range of topics covered. The kinds of literature or policy reports that are relevant in a significance section will also depend on your topic. Throughout this chapter, several examples will be included for each piece of the proposal to give you a sense of what will work for different kinds of topics. Senior researchers who review proposals and program officers recommended several general strategies for significance and aims sections of the proposal:

- **Use both academic literature and well known policy reports in your significance section.** The kinds of reports that have impact would be a blue ribbon panel report, white paper, or workgroup report from the white house, NIH, or the Institute of Medicine (IOM). A major report from a major advocacy group for the Institute where you are seeking funding would also show a major health concern. For example, if you are writing a proposal for NCI, a major report on the problem you are addressing by the American Cancer Society would be appropriate. For NHLBI, a report from the American Heart Institute or for NIA, something

from AARP. The point is that you are looking for reports that are recognized as scientifically sound and well known in policy circles.

- **Do not use literature from obscure journals or reports from organizations that are not well known or considered biased.** All of the literature you cite should be from sources that will be well respected by scientist and policy makers. This includes primarily citing literature from first or second tier journals. Policy reports should come from sources respected for quality research and unbiased work. For example, if you were doing a study on the impact of limited green space on physical activity, a report from the Urban Institute or Brookings would be better to cite than from a local parks association.

- **Link your goals and objectives to a timely public policy concern.** For example, DISPARITIES IN CANCER SCREENING: THE ROLE OF MEDICAID POLICY states that it is investigating the impact of the Affordable Care Act on breast cancer screening. SUBSTANCE USE IN RESERVISTS SOCIAL AND ENVIRONMENTAL INFLUENCES addresses the current concerns expressed in the media and policy circles about the impact of multiple tours in Iraq and Afghanistan on members of the army reserve and their families. DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES? uses the current NIH priority and first lady's policy concern regarding obesity as one major hook for the project.

- **Link Aims, goals and significance throughout the proposal**.

- **Aims should have concrete, preferably measurable outcomes that will make a difference to public health or a particular health issue.** For example, the Medicaid policy study hopes to demonstrate how certain policy choices lead to increased cancer screening while the Parks and Recreation project plans to provide concrete data on how various strategies by urban parks increases or decreases park use in low income neighborhoods.

- **Aims and goals should be stated exactly the same way throughout the proposal.**

SPECIFIC AIMS NAIL DOWN THE STEPS

Direct from NIH:

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Follow the page limits for the Research Strategy in the Table of Page limits at http://grants.nih.gov/grants/forms_page_limits.htm unless specified otherwise in the FOA.

What this means:

In this section, NIH indicates that you should briefly list your research's specific objectives, which may include the following:

- test your hypothesis or explore a research question
- solve a specific challenge
- challenge an existing paradigm or clinical practice
- address a critical barrier to progress in the field
- develop new interventions

Individual NIH Institutes, Centers or Offices (ICOs) may have additional suggestions for crafting your Specific Aims. For instance, the National Cancer Institute (NCI) indicates that your Specific Aims should cover the following:

- broad, long-term goals;

- specific objectives and hypotheses to be tested;

- expected outcomes; and

- impact on the research field

NCI further recommends that your Specific Aims should include the following sections:

1. Brief narrative to describe the project's long-term goals and the hypothesis(es) to be tested, which you should adequately support with citations and preliminary data. Explain how you will use the results to test the hypothesis or answer your research question.

2. Numbered list of the aims. For clarity, each aim should consist of only one sentence. Use a brief paragraph under each aim if you need to provide detail. Most successful applications have two to four Specific Aims. And be sure that all aims are related — but not necessarily dependent upon each other.

3. Brief statement regarding the overall impact of the research.

TIP:

Keep in mind that reviewers usually receive a small, focused project better that a diffuse, multifaceted project.

Specific Aims are almost always limited to a single page in length, unless otherwise stated in the FOA.

Keep in mind that reviewers usually receive a small, focused project better than a diffuse, multifaceted project.

Some reviewers have called the Specific Aims the most important page in your entire application because it may be the only section unassigned reviewers read to understand your Approach, Innovation and Overall Impact. They may make up their minds immediately whether your work should receive funding, and then read the rest of your proposal searching for details to reinforce their initial opinions.

If they immediately determine that they like your project, they will look for supportive points they can put in their review. On the other hand, if they decide they do not like it, they probably will begin to search for faults.

The Specific Aims is a one-page document that you will upload in the Research Plan Attachments area of the application.

Format Note: The Specific Aims section must follow the general application formatting requirements. You must use one of the following fonts in 11 point size or larger:

- Arial
- Helvetica
- Palatino Linotype or
- Georgia

You may use a symbol font to insert Greek letters or special characters, but the font size requirement still applies. In addition, there can be no more than 15 characters — including characters and spaces — per inch. And there can be no more than six lines of text per inch, using at least half-inch margins on all sides of the 8½" x 11" page.

Aims need to be presented clearly, concisely and lead to a very specific goal. The more vague your aims, the less likely you are to be funded. The following example shows how social and behavioral science proposals with very different goals and objectives describe their specific aims:

From NIA sponsored project 1R01AG041955-01A1 Understanding How Personal Networks Change:

SPECIFIC AIMS

Personal networks affect individual health by providing social support and by imposing social burdens. Yet, we know little about how the composition and structure of individuals' networks change over time, how people maintain and rebuild their networks, with what consequences to health, for what sorts of people. Almost all existing studies of any size use scant, summary assessments of networks and few are longitudinal; no American studies combine in-depth network measures in a large panel. The existing shallow measures cannot validly capture the complexity of dynamic networks. This study will fill this lacuna.

Substantively, the long-term goal of this research is to understand which life events, including health events, lead to which kinds of network reconstruction (e.g., expansion or contraction, shift to or from kin, more or less specialization of alters) for what groups (by age, gender, education, etc.) with what health outcomes (e.g., morbidity, mobility, psychological well-being). Methodologically, the long-term goal is to establish the utility of a richer network-describing technique and, additionally, the practicality of using web-based survey methods to do so.

The rationale for this research emerges from the limitations of earlier personal network analysis: is network composition the facilitator of social and health well-being or do health characteristics lead to network composition? Our central hypothesis is that some life events - particularly around employment and family status - lead to a restructuring as roles change, alters leave, or health changes disrupt personal networks. We plan to both test this central hypothesis and respond to the need for detailed panel data on networks by pursuing the following specific aims.

Specific Aim 1. Accurately and fully measure the main trends and main variations in network change among specific populations undergoing major life-

course developments. We do this by (a) fielding a panel study of 600 21-to-30 year-olds and 600 50-to-70 year-olds with three interviews over four years in order to detect change, and by (b) using an extensive name-eliciting procedure for measuring egocentric networks. This will yield a picture of the standard developmental sequences (e.g., a shift from friends to kin among the older respondents) along with variations (e.g., less for women than men).

Specific Aim 2. Identify the causal connections between traits of networks and changes in those traits (e.g., size, kin-focus, support) and health conditions and changes in them (e.g., mobility, subjective health status, depression). The panel structure will allow untangling of causal structures underneath correlations, and will enable multiple topics of inquiry beyond the original scope of this work.

Specific Aim 3. Identify standard patterns and variations in when and how personal networks respond to life events (e.g., job transitions, marriage, deaths of intimates). We ask about events, measure many dimensions of networks, track the continuity of alters, and assess the supportiveness of the networks. The findings will tell us who can rebuild networks after disruptions and how they typically do it (e.g., educated respondents replace lost friends with friends; less-educated with no one or kin). Connected to the health data, the results will show whether and how network dynamics account for the health effects of life events.

Specific Aim 4. Test the practicality and validity of using web-based name-eliciting network techniques. The proposal incorporates an innovative switching design from face-to-face to web interviewing.

These aims will yield the following expected outcomes. First, this panel data will enhance personal network analysis. Second, the data will facilitate many areas of further research beyond the initial goals of the investigators in this project. Third, understanding the consequences of life events will inform both societal awareness and public policy regarding at-risk individuals. Fourth, the results will inform future researchers' decisions about mode effects to be weighed with cost considerations in doing such network research, such that the results can be used to advance both total network and ego-centric network studies.

From NCI sponsored project 1R01CA78980-01 DISPARITIES IN CANCER SCREENING: THE ROLE OF MEDICAID POLICY:

There are substantial disparities in breast and cervical cancer diagnosis, treatment, and outcomes in the United States by race, ethnicity, socioeconomic and insurance status. While mortality rates have fallen over recent decades due to improved screening and treatment, these benefits are not distributed equally across the population. Despite the existence of programs aimed al screening underserved women (e.g., the National Breast and Cervical Cancer Early Detection Program), many eligible women are not reached and research shows that significant disparities in screening remain. [1,2] Medicaid coverage for low-income women may play an important role in ensuring access to screening, though supporting evidence is limited and does not address recently enacted and proposed changes in patient eligibility, physician payment and patient cost sharing.

The Patient Protection and Affordable Care Act (ACA) of 2010 aims to expand health insurance coverage substantially. The ACA has a strong focus on disease prevention and includes several provisions related to women's health. The law gives state Medicaid programs incentives to eliminate cost sharing for preventive services, and will increase physician payment for primary care under Medicaid. However, existing evidence on the effect of changes in coverage on breast and cervical cancer screening is mixed, [3-5] and there is little evidence on how financial incentives such as cost sharing and physician reimbursement affect rates of screening among low-income, publicly insured women. Current variation in state Medicaid programs and anticipated changes under the ACA provide natural experiments for studying the effect of public insurance on screening for low-income women. Public insurance programs vary substantially across states in both eligibility rules and plan features including physician payment and cost sharing; there is baseline variation in the generosity of Medicaid coverage and there is likely to be variation in future Medicaid expansions as some states choose to expand under the ACA while others maintain current eligibility levels.

In this study, we examine how existing and new policies that affect the generosity of state Medicaid programs impact breast and cervical cancer screening among low-income women. We consider the effect of pre- and post-reform variation in eligibility between and within states, as well as the effect of physician and patient financial incentives on screening. In addition, we study how variation in Medicaid generosity across states and over time is related to outcomes such as stage at diagnosis, the single most important predictor of survival. The study will address the following aims and hypotheses related to policy changes affecting coverage:

Aim 1: Examine the effect of state Medicaid eligibility on breast and cervical cancer screening rates among low-Income women.

> H_1: Screening rates among low-income women are higher in states with expanded Medicaid eligibility for parents and childless adults.
>
> H_2: Socioeconomic and racial/ethnic disparities in screening decrease among low-income women in states with expanded eligibility.

Aim 2: Assess how physician and patient financial incentives affect the receipt of breast and cervical cancer screening among low-income women.

> H_1: States with higher Medicaid reimbursement rates have higher rates of screening.
>
> H_2: National increases in Medicaid primary care reimbursement rates (such as those anticipated under the ACA) will increase screening rates.
>
> H_3: States with lower patient co-payments have higher rates of screening.

Aim 3: Examine the effect of Medicaid generosity on breast cancer stage at diagnosis and breast and cervical cancer incidence for low-income women.

> H_1: Women in states with more generous eligibility, payment, and cost sharing will be diagnosed with breast cancer at earlier stages.
>
> H_2: States that expand Medicaid will experience lower rates of breast and cervical cancer incidence among women in low-income counties.

Findings from this study will provide evidence about the impact of public policies on cancer screening for underserved populations. We will be the first to explore the effects of recent Medicaid policies on breast and cervical cancer screening and diagnosis among low-income women. The outcomes we consider will also serve as an indicator of the effect of health reform on prevention and women's health.

From NIAAA sponsored project 1R01AA021136-01A1 A RANDOMIZED CLINICAL TRIAL OF CULTURALLY TAILORED MI:

Primary Aim 1: Treatment Main Effect. Determine the efficacy of standard motivational interviewing (Ml) compared to culturally tailored Ml (CTMI) at two, six, and twelve month follow-up. We hypothesize that CTMI participants will report fewer alcohol-related negative consequences and fewer heavy drinking days at follow-up vs. Ml participants.

Primary Aim 2: Explore acculturation stress as a moderator of alcohol treatment outcomes for Latinos. We hypothesize that among participants with high acculturation stress, those in CTMI will improve more over time than those in Ml (at 6 months). We also hypothesize that among those who receive CTMI, those with high acculturation stress may show greater improvement over time (at six months) than those with low acculturation stress.

Overcome Specific Aims Challenges

There are several common challenges that applicants face — and proven ways to overcome them — that specifically apply to their Specific Aims, including the following:

Challenge 1: If your reviewer reads your Specific Aims and finds them interesting but remains unconvinced, she likely will read the rest of your application to determine if your project is feasible. Therefore, be sure to end the page with a brief paragraph that states your work's impact — that is, how your project, if successful, will change your field of research. Spelling this out for the reviewer allows them to easily grasp your proposal's strengths without having to work for it.

For example, the introductory paragraph on both of the examples above, explain why the problem is important. Each of the aims is very carefully described. In the social network study, the specific activities that will achieve that aim are briefly outlined in plain language. The Medicaid policy study gives the aim in plain language, then uses hypothesis to clearly show what the study will examine.

Challenge 2: Reviewers often make the following comment on the summary statement: "If the first Specific Aim doesn't work, the whole proposal goes out the window. If the researcher doesn't get a positive result with it, he or she can't do aims 2 or 3, so we're not going to fund this until we see the data that have basically finished aim 1."

If the aims follow each other so that Aim 2 follows Aim 1 and Aim 3 follows Aim 2, you must tell the reviewers what you intend to do if you get an unexpected result with Aim 1. Convince them that there is a future to your proposal nonetheless.

The best grant applications are those with interconnected — but not interdependent — aims. Reviewers look for those experiments where the results do not particularly matter because the various outcomes are equally interesting.

STRATEGY:

If the aims follow each other so that Aim 2 follows Aim 1 and Aim 3 follows Aim 2, you must tell the reviewers what you intend to do if you get an unexpected result with Aim 1.

For example, interconnected Specific Aims might include the following:

From NHLBI sponsored project 1R01HL114432-01A1 DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES?:

This proposal is in response to PAR-10-136: Behavioral and Social Science Research on Understanding and Reducing Health Disparities (R01). **Although routine physical activity is critical to optimal health, our preliminary studies indicate that residents of low-income communities in Los Angeles and other cities like Chapel Hill, NC, Columbus, Ohio, Albuquerque NM, and Philadelphia, PA** are less likely to exercise than those in high-income communities. **In particular, low-income groups in Los Angeles with access to public parks are less likely to use their neighborhood parks, even when the parks are within walking distance.** Parks in low-income Los Angeles neighborhoods tend to be smaller and serve a greater population density, but even after accounting for size and population served, they are still used less than parks in wealthier neighborhoods. Parks in lower-income areas had fewer part-time staff and offered fewer programs and organized activities than parks in higher-income areas. However in four other cities, although parks in high poverty neighborhoods were consistently smaller than those in lower poverty neighborhoods, the staffing patterns, programming and use frequently differed. **In some cities, low-income neighborhood parks had more staff and activities than those in high-income neighborhoods, potentially mitigating disparities in physical activity.**

Regular physical activity contributes to a variety of positive health outcomes, including increased longevity; slower functional decline; lower incidence of cardiovascular diseases, diabetes, depression, and certain cancers; and obesity prevention [1]. Neighborhood parks have been identified as a popular setting for engaging in physical activity. Studies show that a significant proportion of local residents report using their neighborhood parks at least once a week and. cite parks as the primary place where they exercise [2,3].

Studies also indicate that park management practices and characteristics are associated with frequency of park use and with moderate-to-vigorous physical activity (MVPA) [4, 5]. However, existing research has been largely cross-sectional and/or has focused on a small number of parks; thus the generalizability of these findings is unclear. It remains to be determined how changes in resource allocation (e.g., programming, staffing, and marketing) can be expected to influence park usage and park-based MVPA. Quantifying the influence of socio-economic status (SES) on resource allocation, changes in park management practices, and park usage in a national sample of parks would help to inform future interventions to promote physical activity at a population level.

We propose to undertake a national longitudinal study of the existence of disparities in park management practices in 25 representative US cities and 200 parks. We intend to advance the state of science regarding the influence of park management practices and shape public policy on health promotion at the population level. Our specific aims are:

1. To determine whether there are systematic differences in park resources, programming, management practices, and park use depending upon the socioeconomic status of park neighborhoods in a representative sample of American cities.

2. To determine whether changes in resource allocation among parks in these cities are distributed equally among high and low income parks, or whether allocation changes attempt to address health disparities among potential park users. We will also determine whether changes in resource allocation are accompanied by changes in park-based physical activity.

3. To make recommendations to the Departments of Parks and Recreation in each city that will support greater use of park facilities among populations who may experience health disparities that can be ameliorated by physical activity.

To accomplish these aims, we will train a cadre of park professionals and members of community-based organizations that support neighborhood parks to act as "citizen scientists" and to collect objective data. Engaging these citizen-scientists in the research process will increase local capacity to reliably measure park management practices, park characteristics, park use, and physical activity. Citizen-scientists are an asset that will endure long after the proposed research (if funded) is completed and could form the basis for research in which future interventions to promote physical activity can be rigorously evaluated. This will be the largest and only nationally representative sample of neighborhood parks ever studied and the first to use a free app that enables local communities to systematically observe and document physical activity in local parks.

Challenge 3: If you are submitting a competitive renewal and change the thrust of your research from the original proposal, tell reviewers why you changed the Specific Aims, and detail your new directions. The reviewer will see the summary statement from the initial award and know your original award's Specific Aims.

Some reviewers are very particular about that, wondering, "Did the Principal Investigator succeed in the first five years?" If not, they likely will not give that PI a second chance. As a result, you must inform reviewers why you changed directions, such as "something came up that was more interesting to pursue" or "a new technology became available".

Crafting Your Specific Aims

The two to four Specific Aims that make up the body of your research plan are the real engine that drives your application. Why is it usually two to four aims?

There is no rule regarding how many aims your proposal should have, but three or four is the average for most NIH R01 applications. Reviewers and program officers interviewed for this guide stressed that two or three are often better for social and behavioral science proposals because of the complexity of the problems

researchers address. The aims also need to be something that can clearly be studied in a three to five year study.

One of the major mistakes that applicants make are proposing too may aims or aims that are too vague. For example, the Medicaid policy study has three very specific aims that measure whether public policy leads to: 1) increased coverage of cancer screenings for women, 2) increased screening, and 3) decreased incidence of cancer. These aims can be measured using the data described later in the proposal. If the researchers stated that their aim was to "Determine if the ACA decreases cancer rates among women," their aim would be too vague and diffuse. Reviewers would ask how the researchers intend to link the ACA to cancer, what kinds of cancer they meant to study, and how they would like a new policy to reduced cancer rates.

With more than four aims, space limitations will not allow you to sufficiently describe your aims to convince reviewers you have fully developed them. More than four aims suggests that you are "all over the place" and don't know what you really want to study. These kinds of "fishing expeditions" are often derided by reviewers as indicating a proposal that is "trying to do too much." Three to four aims support enough research questions or hypothesis-testing strategies and description within the application and better support the number of researchers under the budget and likely three to five year project duration.

You might consider using a standard format for each of your aims using separate sections. One reviewer recommends breaking your aims down into the following:

- **Rationale** — This provides the strategic context, meaning what you are trying to show and why. This is also the place where you defend the specific approach you plan to use, consider alternatives and begin to describe your logic in designing your experiments.

TIP:

Two to four aims that are clearly doable in a three to five year time frame allow enough space for description within the application and suggest a project that will have clear, measurable outcomes on health or public health issues.

- **Approach** — Here, detail how the research will be performed. Try to build reviewer confidence that you can carry it out. For established investigators, you can highlight key papers in your bibliography that support your experience in the proposed techniques. New investigators either must show preliminary data demonstrating such familiarity or recruit collaborators with widely-acknowledged expertise in the method.

- **Outcomes and Alternatives** — Use this section to describe your projects' potential results and their implications for your proposed model(s).

You should also consider including a research flow chart or time line that provides a glimpse into the broader strategic thinking guiding your project.

For example, from NHLBI sponsored project, 1R01HL114432-01A1 DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES?

<u>**Tasks and Timeline.**</u> We propose a four-year timeline for completion of the study. Table 1 displays our proposed timeline, broken down by study year.

Study Year	Task
Year 1	- Select 200 nationally representative parks - Recruit and train 25 data collectors and 25 back-up data collectors, map parks - Collect data in parks, monitor quality; **conduct key stakeholder interviews**
Year 2	- **Analyze baseline data; conduct make up data collection as needed** - **Report initial findings to localities and to local Departments of Recreation and Parks for feedback. and interpretation**
Year 3	- **Recalibrate data collectors with booster training** - **Collect second wave of data in parks, monitor quality; conduct key stakeholder interviews**
Year 4	- **Report second wave findings to localities and to local Departments of Recreation and Parks for feedback and interpretation** - Finalize analyses and reports incorporating local feedback - Prepare manuscripts, disseminate findings

RESEARCH STRATEGY HAS 3 PARTS

Direct from NIH:

Organize the Research Strategy in the specified order and using the instructions provided below, or as stated in the Funding Opportunity Announcement. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section (Part I Section 4.4.9).

Follow the page limits for the Research Strategy in the Table of Page limits at http://grants.nih.gov/grants/forms_page_limits.htm unless specified otherwise in the FOA. Note that the page limit for this attachment will be validated as a single file.

(a) Significance
- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

(b) Innovation
- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

(c) Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the Resource Sharing Plan attachment below, include how the data will be collected, analyzed, and interpreted.

- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.

- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.

What this means:

Your 12-page Research Strategy section will have three main parts:

1. Significance
2. Innovation
3. Approach

These correspond to three primary criteria NIH reviewers use to evaluate your proposal, and you should begin each section with the corresponding subheading.

In addition, your Research Strategy will also include a Preliminary Studies section (if it is a new application) or a Progress Report (for renewal and revision applications). You can address these by including the appropriate subheading —

Preliminary Studies or Progress Report, depending on the type of application — within one of the main sections listed above.

Example of Combined Significance and Approach Sections for Each Aim

From NIA sponsored project 1R01AG041955-01A1 Understanding How Personal Networks Change:

3a. Aim 1: Measure the main trends and variations in personal network change.

3a. 1. Introduction. *Using in-depth and broad name-eliciting techniques, the objective of Aim 1 is to map, at three waves, the personal networks of two respondent populations – 21-to-30-year-olds and 50-to-70- year-olds – undergoing major developmental changes.* This strategy will yield unprecedented information about the dynamics of social support networks. To appreciate the need for and the innovation of the proposed project, we briefly review (a) how Important personal networks are to physical and mental health, and (b) how current studies of network dynamics and consequences are limited by the nature of their samples and, more, by their network measurement approaches. We then proceed to explain the research design and measurement procedures that meet the need and the expected fruit of the research.

3a. 2. Justification and Feasibility. *Designs for Studying Personal Networks. A preliminary consideration that needs addressing is the choice to study personal, egocentric networks rather than whole, group networks.* Since its post-war emergence, social network analysis (SNA) has entailed two distinct approaches. One, originating in the anthropological tradition (e.g., Mitchell, 1969; Boissevain, 1974), involves mapping the multidimensional, egocentric networks of individuals (e.g., early studies such as Laumann, 1973; Wellman, 1979). The other, largely in the organizational literature, involves mapping specific ties in a closed population – such as trust in an organization (e.g., Lusher et al., 2012), scientists' citations in

a discipline (e.g., Brieger, 1976), or STD transmission in a school (Bearman et al., 2004). *Each approach is suited to answer different questions....*

A different concern, for both SNA approaches, is the accuracy of respondents' reports. In the ideal study, each key relationship's described by a respondent would be cross-checked with the alter. A few studies have done this on small samples (initially, Katz and Lazarsfeld, 1955; Laumann, 1973) and have revealed the scale and type of errors (e.g., people are good reporters of their friends' ages but not their politics). Doing cross-checks for a study such as this would be immensely difficult and make only a small sample affordable – for relatively little payoff. A half-century on, we have a good sense of where the errors lie. Moreover, the in-depth name-eliciting procedure used here yields greater reliability than the typical short-form or single name-eliciting question method used in the literature (McCallister and Fischer, 1978; Killworth et al., 1990; van Sonderon et al., 1990; van Groenou , et al., 1990).

Networks and Health. I*ndividuals' personal ties affect their physical and mental health, and quality of life* (reviews include: Pinquart and Duberstein, 2010; Cohen and Janicki-Deverts, 2009; Christakis and Fowler, 2009; Berkman; 1995; Berkman et al., 2000; Schwartzer and Leppin, 1992; illustrative studies include Maulik et al., 2011).…

On-going, large-scale, longitudinal American data-sets include network measures, but they have their own limits, largely being limited to a few summary measures: [List of studies and the measures they created]

These major, longitudinal data-sets[5] can at best provide only partial network measurements, simply because they devote only a few minutes of their interviews (or just a page or two of their paper-and-pencil questionnaires) to measuring networks. Most get only summary assessments. The two name-eliciting questions used in NSHAP and SHARE are an advance but still provide partial glimpses rather than full maps of networks. Moreover, the **rationale** for this proposed study is that *none of the data sets mentioned here was designed with the goals of*

this project, to assess network dynamics and their consequences during rapidly changing developmental periods.

3a. 3. Analytic Strategy to Meet Aim 1. Using in-depth and broad name-eliciting techniques, the project will map, at three waves, the personal networks of two respondent populations – 21-to-30-year-olds and 50-to-70-year-olds -undergoing major developmental changes.

- Target Populations. We focus on 21-to-30 year-olds and 50-to-70 year-olds because, they provide two concentrated populations undergoing especially substantial life changes - in activities, family status, residence, and so on -- with accompanying changes in social connections, albeit of strikingly different kinds. We use a narrower age range among the young because so much volatility exists in that decade; important life events are more stretched out over time at older ages so we use a 20-year range there.

- Three Waves. We need three waves, 18 months apart, rather than only two *in order to (a) track the reconstruction of networks due to change.* We expect many respondents to experience between t(1) and t(2) certain network disruptions – e.g., loss of friends due to job move, death of parent – which will show up as "holes" at t(2). And we expect many of these respondents – which ones an being an important research question – to fill those holes, say someone to confide in, by t(3).

- Sampling and Recruitment: *We will interview 21-to 30 year-olds and 50-to- 70 year-olds in three waves, 18 months apart. We use mixed interview modes in an explicit experiment….*

     This design will, of course, face complications. We will modify standard web sampling to get respondents in the sample regions, track both sets of respondents, travel to conduct FTF interviews with respondents who have moved where feasible. If need be, these will be given a web-based survey and flagged for the change in group assignment. We will also provide

training to respondents who shift from FTF to web. Conditional on the outcome of the first three waves, we would seek funding to follow the subjects longer. Because not all people can be randomly assigned to a web survey, there will be a need for weighting to adjust, as older persons are not as likely to have regular internet use at home. This mode-weighting will be in addition to standard weighting to match the samples with known distributions across key demographics of 21-to-30 and of 50-to-70 year-olds in the region.

- The survey instrument will yield new, detailed, longitudinal data on individuals' personal support networks. Appendix A presents an initial draft of the screening survey instrument, and Appendix B contains the initial draft of the full questionnaire for wave 1. Much of the first year of this project is devoted to fully developing and testing this survey for use in two modes of data collection - face-to-face and web, and for two populations, older and younger persons. The usual demographic and background questions are, of course, included, most often adapted from the GSS to provide benchmarks. The key sections are:

  - Personal Network Questions. We will and improve the name-eliciting technique from the Northern California Communities Study (NCCS, Fischer, 1982a), which later studies have shown to be best for assessing personal networks (Kmworth et al., 1990; van Sondoren et al., 1990; van Groenou et al., 1990; Campbell and Lee, 1991;. van der Poel, 1993), although it is, of course, much more time consuming than summary ratings typically used in mass surveys. The NCCS used 11 questions to elicit the names of people with whom respondents were involved. The questions ranged in topic from who would pick up respondents' mail if they were out of town to who might lend them money. This procedure yielded an average of 18.5 names. Then, the interview asked a series of questions about all the named people, such as how they knew those people (family, work, etc.), which were men or women, and which lived nearby. Interviewers extracted a subset of ties

for more extensive questions - for example, how the two had met and how often they got together.[8]

As to *improvements* on the NCCS: (a) Later work (e.g., van der Poel, 1993; Marin and Hampton, 2007) suggests that somewhat *fewer* questions rather than the original 11 might still yield accurate results. (b) We will modify questions to insert *more explicitly health-related support and exchanges*. These modified name-eliciting questions are noted in Appendix B. Depending on time availability, we could add more questions about health behavior. (c) We will add *two distinctly new questions*. One specifically elicits *burdensome ties* (Rook, 1984). Another specifically asks about alters who are largely contacted via e*mail, internet, or social media*. (d) We will add, in waves 2 and 3 questions about people who were named in the previous wave but not repeated and about people who appear for the first time. (e) We ask questions tapping respondents' *feelings toward their social lives* and how supported they feel. In particular, we use the NIH Comorbidity survey's items on how much respondents feel they can count on friends and relatives (Kessler et al., 2004).

The result will be many *measures of respondents' networks* from simple ones like size and support to complex ones like density, homophily, reciprocity, and turnover rates, to name just a handful. They will be oriented to the health arena, but will also support inquiry into other aspects of network change, such as educational attainment, labor force participation, and social activities. Critically, the method also yields a second data-set, *measures of specific ties*, enabling dyadic analyses - looking at the patterns and consequences of, for example, ties that are homophilous or ties that are formed at school.

- Health Measures. We have borrowed or adapted a long set of health measures from HRS and to a lesser extent, ADD Health. They cover chronic and acute health conditions, including treatment regimens; functioning, such as the ability to walk well; health behaviors, such as smoking and exercise; depression (the K6 version of the CES-D depression – Kessler et al., 2002; Cole et al., 2004); and begins with the well-validated self-rating of health (Jylha, 2009; Benyamini, 2008).

- Personality. Personality differences shape social engagement. We will use an abbreviated form used by GSS and others of the standard "Big Five" personality scales (see John et al., 2008; Crede, et al., 2012). A version of the UCLA Loneliness scale provides a measure distinct from depression (see Hughes et al, 2004). We will use one of the classic measures of internal vs. external locus of control (sense of efficacy), which has been shown to have important social and health consequences (Gecas, 1989; Lefcourt, 1992: Gale et al., 2008). Finally, the GSS happiness item is a standard, brief measure of subjective well-being.

- Life Events Inventory. To avoid conflation, we must distinguish life events as "external shocks" in three categories: social events (marriage, divorce, new child, parental divorce or death, etc.), health events (e.g., accidents, illness), and largely independent events (e. g., job loss/gain, retirement, graduation, fire, incarceration of self or intimate). Some life events and life cycle transitions (such as union, marriage, and divorce) will be known in the normal course of re-interviewing. But we will present a checklist of important occurrences in respondents' lives between before and between interviews. A few Inventories (Goldberg and Comstock, 1980; Bieliauskas, et al., 1995) suggest that the most common major events include deaths of kin or friends, births in the family, changes of job or business, and moves. In pretesting, we will refine and shorten these lists and adapt them. Rough estimates drawn from surveys suggest that between each wave we should have among

the older sample about 40 retirements, 60 moves, 100 hospitalizations, 50 deaths in the immediate family, 60 reports of financial distress; and 30 reports of marital problems, as well as deaths of friends, marriage of children, job changes, income shocks, accidents, serious Illnesses, and the like.9 In the younger sample, we can expect many school, work, and household arrangement transitions between each wave. There are likely to be, in addition, about 100 deaths of friends, 100 hospitalizations or other serious illnesses, and about 10 deaths of parents.10 About 150 to 200 respondents among the older and more among the younger should experience at least one major event we can anticipate; others would have minor ones including the departure of friends, incidents at work, disputes with spouses, and so on; the numbers would be much higher for the younger sample. The 18-month windows enable us to capture both short-term responses and longer-term adjustments. Following Turner and Avison (1992), we will add two or three follow-up questions asking respondents which of these events affected them the most and whom, if anyone, did they turn to for support or celebration. We consider it critical to thoroughly pretest and pilot-test the instrument and have built that into the schedule. We plan to use 50 cases each of pilot tests on the FTF and the web format with diverse respondents.

- Modeling. Network data over time pose complex statistical issues. Specific ties are nested within waves and waves are nested within individuals (e.g. van Duijn et al., 1999).

  Aim 1 entails describing *main trends* and *main variations* in network change among specific populations undergoing major life-course developments. What are the main, developmental trajectories for various network dimensions - size, composition (e.g., percent kin, nonkin; local v. distant ties; context; duration) support and exchanges provided density, stability, etc.? Examples of hypotheses:

- As older respondents age, mean network size declines, percent kin increases, density increases, sociability declines.
- There is less in the literature to suggest hypotheses for the young, but we might speculate, for example, that: (a) they have greater network turnover level the older do; (b) turnover declines over time; (c) ties with workers increase, and so on.

3a. 4. Expected Outcomes for Aim 1. This procedure will yield an unprecedented rich and accurate description of how personal networks, at the level of networks and at the level of specific ties, change during periods of accelerated adult development. It will also describe key variations by demographic and cultural subgroup in those network trajectories. Given the connections between support networks and health, these baseline descriptions allow us to understand the coping resources and lacunae during key periods of the life course. This procedure will also provide a data-set for other scholars to explore yet further details of the process.

This example interweaves significance for each aim with a very detailed discussion of methods for data collection and analysis. The authors justify the methods, sampling strategy and other aspects of the study through discussion of their method as it relates to already existing research. Appropriate studies are cited throughout. Note that while the application proposes an innovative strategy to collect data on social networks and understand their impact of health and other aspects of life, they are not proposing completely new methods. Instead, they build on existing measures and research, modifying existing strategies to gather new data which will significantly move their field forward. They also candidly discuss the potential problems with their choices for sampling, data collection and analysis and justify why they think their choices are best. Each of the other aims in the proposed study are described in the same way.

Pilot Study Data

NIH R01 proposals usually are built on smaller pilot studies or single site studies done previously by members of the research team. Pilot or preliminary study data is a critical component of a successful application as it shows that your project can be done. While pilot data should provide some preliminary answers for your proposed R01, you must be clear that you either could not answer all of your research questions or need more data to answer them. Otherwise, reviewers might wonder why you need to do the larger study if you already have answers from your earlier research. In presenting pilot study data, researchers should be clear about its relationship to the larger study. For example, if your pilot only included a few cases, the goal of the R01 is to prove your tantalizing preliminary findings through a full R01 study with a larger sample. If you or other researchers have done similar studies in one location, your multi-site study will explore the generalizability of your earlier findings. If your earlier research developed a new tool and did some pilot testing, your R01 will fully test your tool with a clinical trial or some other form of recognized survey research.

NIH allows you to choose to present the Preliminary Studies/Progress Report aim-by-aim or in a section by itself. Keep in mind, however, that veteran reviewers likely will be most comfortable seeing it as a separate section because that is the way they are used to seeing it before the application form changed in January 2010. Consequently, this currently tends to be the more effective strategy.

As you write your proposal, however, you may find that you are describing an aim in the Specific Aims section, and you need to reveal a particular piece of preliminary data to establish your aim's feasibility. You could place the data discussion within the specific aim, or you could include it within a large section of Preliminary Data and reference the specific aim with a statement such as, "our pilot study provided preliminary answers to aim 1: understanding how networks for families of transitioning youth with autism are different between youth who successfully enter a program within six month of completing high school vs. youth with no transition programming."

Page Limits and Lengths for Each Section

Although NIH does not assign page limits for each section, it does suggest that you break up the 12 pages as follows:

- Significance — 10-15 percent (1-2 pages)
- Innovation — 15-20 percent (2-2½ pages)
- Approach — 33-50 percent (4-6 pages)
- Preliminary Data/Progress Report — 25 percent (3 pages)

Keep in mind, however, that these are merely NIH's recommendations. You may find that you need more room for your Approach or Significance, and must take the needed space from another section. For instance, one reviewer recommends presenting a shorter Innovation and using that additional space to better detail your Approach or to show additional data.

CRAFTING AN EFFECTIVE RESEARCH STRATEGY SECTION FOR A SOCIAL SCIENCE PROPOSAL

Social and behavioral science R01 proposals face a particular challenge because the range of topics that might be suitable for an R01 is so broad and social and behavioral scientists have many methods to choose from in developing their project. Since NIH review panels are organized by topic, not scientific discipline, many of the people on the review panel that will make a decision about your proposal may know very little about the research literature in your discipline related to the topic or your methods. That means that you need to convince a group of people who know about your topic, but may not be experts in what your project can contribute to that topic, that your proposed research will provide important new insights that will both move forward the science on that project and make a difference to a specific issue in health or public health. One senior researcher and peer reviewer noted that the trick to writing a successful social or behavioral science proposal is to:

> *Keep until the day you submit honing and crafting the single goal of the project and how it is going to advance science. [You need to] build a story line about what's gone before. Reviewers want 15% of your application to speak to the societal relevance [of your approach], 85% showing the significance of your specific project and how that relates to what's been done before. Each of these hooks from the initial abstract, aims sections, and significance should build in to your design. Your proposal should answer the questions:*
>
> a. *What do we know?*
> b. *What do we need to know?*
> c. *What are the gaps in knowledge where research needs to be added?*

Program officers emphasized that the project did not just need to fulfill a gap in the literature, but to answer a question that is relevant to NIH. One

program officer commented: "Explain what your research question is and why it is important to answer that question. An important topic is not enough – it's picking an important research question." An important research question is one that responds to a priority at NIH and the Institute that you hope will sponsor your project. As discussed in earlier chapters, researchers need to do their homework and understand what is important to NIH when developing their research questions. You may even echo the exact words of the priorities for NIH or the IC you hope will sponsor your project. Your research question needs to be timely and link to policy literature that shows how important the topic is.

A common problem for social and behavioral science proposals is identifying a research question that is broad enough to make an impact on your topic, but specific enough that it can be understood as a concrete, doable project by those reviewing the application. One of the biggest problems reviewers and program officers see is "research question and specific aims that are unclear or much too complicated. This is one research project not an entire career. [They try to] cover way too much more than any team is equipped to handle." As one program officer commented:

> *Your Impact or results statement (significance) [should address the] "So what questions." The project needs to be something that either moves science forward or it will have an outcome for health. That needs to be concrete. [You need to show that your project] probably is going to reduce the incidence of X disease and say how it is going to do that. Perhaps [the project] will help to improve ways of communication between lab and clinicians, providing a mechanism so that information gets transferred clearly and in a timely manner. Not grandiose, doable and focused. A good question is clear, verifiable (or not), and if it is not a hypothesis that can be proved through statistical analysis, it is something that you can test with some confidence. Fuzzy results don't help anybody. [Your project needs to be] clear, concisely presented, and focused on something pretty specific.*

NIMH, the largest funder of social and behavioral science research has recently changed its priorities to focus on projects that provide concrete evidence that

will change something significant in science for practice. One program officer commented:

> *NIMH shifted the science approach to asking all applications to identify the target or methanism of change. [This means] This new approach is designed to specifically identify what is going to make change. On services or systems levels [would this be answering]? What does this intervention do to manifest change? What is the unique target or mechanism that turns the key? Identify what it is that is the 'magic or unique ingredient' that enhances child or adult mental health outcomes. Here's what's new, here's what I am testing. Tie the target to an overall concept, measures, and outcomes– embedding into [each aspect of your project] design [how you are going] to capture the mechanism for change.*

As these quotes suggest, a successful proposal addresses issues that are not just the concern of social and behavioral scientists. Peer review panels intentionally include people who are experts in a topic area from a broad range of backgrounds, including biomedical and social scientists, clinicians, and sometimes advocates for a particular disease. One regular review commented, "There is a misconception that reviewers are experts [in your scientific field], that each asks the same questions. You have to address several audiences [in your proposal]. Instead, you should be focused on a problem that is recognized by people from all disciplines – scientists, policy makers, and practitioners – as something that really needs to be solved." This may be difficult for social and behavioral scientists caught up in disciplinary battles over theory or who feel that they need to argue that their discipline has the right approach to study a topic. As one person who has chaired peer review panels for years noted:

> *There are a lot of social science reviewers now. [Applicants] get into more trouble [by arguing about] interdisciplinary issues like [the benefits of] sociology vs. anthropological [approaches or] phenomenological vs. survey research. Highlight how I am contributing to the specialty area that I am in rather than bashing other methods.*

As this advice suggests, social and behavioral scientists have a lot to do in the 12 pages allotted for significance, approach and impact. You need to present a clear, doable research project with a research question that you can show will make an important contribution to a general field of health science inquiry. You need to make an argument for the significance of your research problem to people who may not know much about your field. You need to explain why you chose the methods you plan to use and clearly explain how they will address your research question to an audience that may know very little about those methods or social and behavioral science in general. You need to show concretely how your research will lead to a measurable or clearly evident change in health or public health. Successful researchers and program officers suggest a few tricks to do this:

- **Ensure that your design, sample, and analysis follow items identified in significance section.** As shown by examples below, this can be done by interweaving parts of the significance into the sample and methods sections of the proposal.
- **Repeat elements of each aim when talking about your justification for the sample, methods and outcomes.**
- **Use exactly the same words to describe your aims and research questions throughout the proposal.**
- **Bold key sentences in paragraph that explain something important in the proposal.** This could be a sentence explaining a how the literature supports your specific aims, your key mix of methods and why they will lead to innovation, or any other key part of the proposal you don't want reviewers to miss.To quote one successful applicant, "You've got to build the case for the significance and innovation [of your project]. You are graded on significance and innovation."

Social and behavioral science proposals generally achieve one of four goals, although applications often seek to accomplish several of these goals in one project:

- **P**roviding fundamental information on a public health issue or practice
- **Providing theoretical grounding for advances in health or public health sciences, methods or practices**
- **Developing new methods to research health or public health issues**
- **Testing social or behavioral science tools that will address a particular disease or condition.** This could include using social science measures to evaluate a biomedical approach or clinical practice. For example, finding out if practitioners regularly use evidence based procedures or learning from patients first hand the consequences of drug side effects to quality of life.

The social and behavioral science funded projects used as examples throughout this guide show how these four goals are addressed in practice. For example:

- NCI sponsored project 1R01CA78980-01 DISPARITIES IN CANCER SCREENING: THE ROLE OF MEDICAID POLICY provides fundamental background information on the impact of public policy innovations on the percent of the population screened for breast cancer and the incidence of breast cancer.
- NIDA sponsored project 1R01DA034072-01A1 SUBSTANCE USE IN RESERVISTS SOCIAL AND ENVIRONMENTAL INFLUENCES provides background information on the impact of substance abuse on reservists and their families and develops a new method to interview reservists and their family members.
- NIMH sponsored grant 1R01MH099190-01A1 FAMILY OUTCOMES IN AUTISM SPECTRUM DISORDERS fundamental information on the impact of ASD on the families of children with ASD as well as exploring some key theoretical issues related to ASD.
- NHLBI sponsored project 1R01HL114432-01A1 DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES? uses a novel multi-disciplinary method to provide background information on the role of parks in health disparities.

- NIAAA sponsored project 1R01AA021136-01A1 A RANDOMIZED CLINICAL TRIAL OF CULTURALLY TAILORED MI provides further testing of a clinical tool using motivational interviewing that is culturally tailored for Hispanics/Latinos to address alcohol abuse and driving while under the influence of alcohol.
- NIA sponsored project 1R01AG041955-01A1 Understanding How Personal Networks Change uses a novel multi-methods approach to provide fundamental background data and explore theoretical issues related to the role of social networks as people age.

The remainder of this chapter will discuss how applicants can write successful significance, approach (methods) and innovation (outcomes/impact) sections of their proposal using these studies as examples. The section also provides discussion of the types of methods that are currently favored at NIH. The methods section dispels the mistaken belief that only quantitative studies that present clear hypothesis are recommended and discusses the advantages of multi-methods research.

Section 1: Significance

Your Research Strategy's Significance should indicate the following, according to NIH:

- The importance of the problem or critical barrier to progress in the field that your project addresses;
- How your proposal will improve scientific knowledge, technical capability and/or clinical practice in one or more broad fields; and
- How your successful project will change the concepts, methods, technologies, treatments, services or preventive interventions that drive this field.

In addition, the National Institute of Allergy and Infectious Diseases (NIAID)

suggests that you consider your proposal's significance both in terms of your scientific field's state and your long-term research goals. With this in mind, the institute maintains you should include the following in your Significance section:

- How your research will advance your scientific field.
- What knowledge gaps your proposal will fill, demonstrating that you are aware of these gaps as opportunities.
- The new and unique nature of your work.
- Your successes associated with related grants.
- How your work meets NIH's mission to improve health through science. Reviewers will ultimately judge your application on your research's likelihood to ultimately cure, treat or prevent disease.

Your strategy for this section will also depend upon your audience — meaning your reviewers' expertise in your field — NIAID notes, pointing to two scenarios:

- Scenario 1 — The study section is narrowly focused in your scientific area, allowing you to write less regarding your research's significance.
- Scenario 2 — The study section is more diverse, meaning you must include more significance information.

Unless you are responding to a specific Request For Applications or you know there is a social science review panel appropriate for your project, you should assume scenario 2 if you are writing a social or behavioral science proposal. Keep in mind that NIH reviewers use this section to assign your application to an Institute for possible funding, and your description obviously will affect that decision.

Further, the National Cancer Institute (NCI) weighs in with these additional tactics for successfully writing this section:

- Carefully review published data in your field and avoid outdated research. Use citations not only as support for specific statements, but also to

establish familiarity with all of the relevant publications and points of view. Someone working in your field may assess your application, and if you do not mention their contributions, they may not favorably review your proposal.

- Highlight your awareness of potential barriers and alternate approaches.
- Point out how others can apply your research to your scientific field and/or related areas.
- Clearly state all public health considerations.
- Demonstrate that you can attain your objectives within your stated timeframe.
- Stress any experimental method innovations, such as new strategies, research methods and/or proposed interventions.

It is important to remember that your significance section is not a traditional lit review where you show that you have read everything related to your field. To the contrary, you need to show in just a few pages that you are both aware of the literature on your topic across a wide range of disciplines and approaches and that your proposed research will fill a gap in the existing literature. That means that your search for literature should look broadly at your topic from both a biomedical perspective and a social/behavioral science perspective. It is also important to include policy perspectives on your topic – not only work published in academic journals but policy pieces from blue ribbon panels or recognized think tanks. Senior scientists highlight that you don't want to cite everything ever written on your topic, but stick with recent literature that was published in respected journals. One seasoned applicant and reviewer commented that, "you don't want to cite publications from 3rd rate journals; that can be the kiss of death."

Your significance section should focus on explaining why your research needs to be done. That means including only literature directly related to your specific research question. The significance section should be building the case for your research. For example, a senior scientist commented that:

"Any of the studies [funded] need to fill a knowledge gap, [or provide] descriptive data on a new phenomenon. You have to know what is out there already and put that in your lit review. Do an in-depth review of lit on what has been done already. Delimit your study [by showing how it will fill a gap in the literature]. You have to build the case from the beginning to end of your proposal."

Significance ≠ Impact

Many investigators are unsure regarding the difference between "significance" and "impact." NIH states that "significance is how important your research would be if everything worked perfectly, and "impact" is the likelihood that the project, as written, will change the relevant scientific field and make a difference in human health.

In other words, "significance" is whether the project is worth doing, and "impact" is what NIH gets for its money at the end of the project.

At the same time, your research cannot have impact if it is not worth doing, so high scores for both Significance and Impact are important indicators for funding. Nonetheless, if your research plan is seriously flawed or reviewers do not think your team has the necessary experience and resources to complete the proposed experiments, then your proposal likely will not have much impact, even if the topic is highly significant.

For example, if your research involves the connection between health disparities and limited physical activity, you can then support this statement with statistics to establish the topic's importance in the reader's mind.

Remember, however, that this section should not look like a book report. You should not perform an exhaustive review of related scientific literature. Although

REMEMBER:

Your research cannot have impact if it is not worth doing, so high scores for both Significance and Impact are important indicators for funding.

you should do a literature review, you do not need to include every paper in your application's Bibliography.

Continuing with the example above, the applicant believes that the lack of resources, appropriate programming, and safety issues in parks near low income neighborhoods lead to children in those neighborhoods getting less physical activity because the parks have less to offer or are viewed as unsafe. In the resulting Significance section — which should take up one or two pages — the investigator would explain how her proposal would expand the field, is new, etc., based upon NIH guidelines noted above. Therefore, this section might outline how this research could lead to concrete data on the resources and safety issues in parks serving various kinds of neighborhoods that could shed light on whether improving amenities and safety in parks in low income neighborhoods can improve physical activity.

In addition, NIH provides the following details to help clarify the difference between significance and impact:

Significance	Overall Impact
Significance is evaluated and scored independently of the evaluation and scoring of investigators, innovation, approach, and environments.	Overall Impact is not a sixth review criterion.
The evaluation of significance assumes that the "aims of the project are achieved" and/or will be "successfully completed." • Moreover, reviewers should evaluate the significance of the project within the context of a (research) field. For example, autism is a significant field of study, but not all studies (projects) of autism are significant. • Research fields may vary widely, so it would be helpful if reviewers identify in their reviews the research fields within which the project addresses an important problem or critical barrier to progress. • The research field may be focused on a specific area (environmental impacts) or a specific disease (e.g., autism), or maybe more broadly defined to cut across many health issues (e.g., language training, psychology).	Overall Impact is not necessarily the arithmetic mean of the scores for the scored review criteria.
	Overall Impact takes into consideration, but is distinct from, the scored review criteria.
	Overall Impact is the synthesis/integration of the five core review criteria that are scored individually and the additional review criteria which are not scored individually.
	To evaluate, the reviewers make an assessment of the likelihood for the project to exert a sustained, powerful influence on the research fields involved, in consideration of the scored review criteria and additional review criteria (as applicable for the project proposed). • Likelihood (i.e., probability) is primarily derived from the investigators' approach and environment criteria. • Sustained, powerful influence is primarily derived from the significance and innovation criteria. • Research fields may vary widely, so it would be helpful if reviewers identify in their reviews the research fields they believe will be influenced by each project.

Perhaps one of the biggest influences on your application's Overall Impact is the Significance section. Therefore, you must tell the reviewer why what you propose is important.

For example, you might begin your Significance section by stating:

There are substantial disparities in breast and cervical cancer diagnosis, treatment, and outcomes in the United States by race, ethnicity, socioeconomic and insurance status. While mortality rates have fallen over recent decades due to improved screening and treatment, these benefits are not distributed equally across the population. Despite the existence of programs aimed al screening underserved women (e.g., the National Breast and Cervical Cancer Early Detection Program), many eligible women are not reached and research shows that significant disparities in screening remain. 1,2 Medicaid coverage for low-income women may play an important role in ensuring access to screening, though supporting evidence is limited and does not address recently enacted and proposed changes in patient eligibility, physician payment and patient cost sharing.

The Patient Protection and Affordable Care Act (ACA) of 2010 aims to expand health insurance coverage substantially. The ACA has a strong focus on disease prevention and includes several provisions related to women's health. The law gives state Medicaid programs incentives to eliminate cost sharing for preventive services, and will increase physician payment for primary care under Medicaid. However, existing evidence on the effect of changes in coverage on breast and cervical cancer screening is mixed, 3-5 and there is little evidence on how financial incentives such as cost sharing and physician reimbursement affect rates of screening among low-income, publicly insured women. Current variation in state Medicaid programs and anticipated changes under the ACA provide natural experiments for studying the effect of public insurance on screening for low-income women. Public insurance programs vary substantially across

states in both eligibility rules and plan features including physician payment and cost sharing; there is baseline variation in the generosity of Medicaid coverage and there is likely to be variation in future Medicaid expansions as some states choose to expand under the ACA while others maintain current eligibility levels.

(From NCI sponsored project 1R01CA78980-01 DISPARITIES IN CANCER SCREENING: THE ROLE OF MEDICAID POLICY)

TIP:

If your research will not affect a large group of people, you can make an argument for transfer of results to other populations — meaning your results could lead to additional developments that would affect larger populations.

If your research will not affect a large group of people, you can make an argument for transfer of results to other populations — meaning your results could lead to additional developments that would affect larger populations. If your proposal involves basic science, this type of Significance reasoning becomes critical.

Now, let's look at sample Significance language, including where many first-time applicants run into challenges:

"Obesity is a growing problem in the United States, with much of the population overweight or obese. *[Here, you should provide additional specifics so that reviewers have a clearer picture regarding just how many people are affected by this and could potentially benefit from your research.]* And estimates are that the problem will get worse. *[How much worse do you think it will get? Be specific.]* Obesity increases the risk for many problems. *[Like what? Explain that.]* In poignant fact, what kills most obese patients is pneumococcal infection. *[That's a known fact, so you need to tell the reviewer how many.]"*

Constructing Your Significance

When writing your Significance section, you should be able to address all of your main points within roughly four paragraphs using the following plan:

- **Paragraph 1:** Introduce the problem you plan to solve.
- **Paragraph 2:** Additional background as needed: Here, cover the most important points that support the first paragraph's information.
- **Paragraph 3:** Hit significance hard by describing the approach that will overcome any difficult challenges.
- **Paragraph 4:** Emphasize the significance in a broader context.

In addition, be sure to use plain language to mention the following:

1. Why the results stemming from your hypothesis and plan are important.
2. How your findings will change science or medicine.
3. If lives will be saved or if the quality of life will be improved and how.
4. What new rationales for treatment you will test and why.

Essentially, tell the reviewer what you are going to achieve that's different.

Learn From This Example

You can refer to the following Significance examples from a successful R01 application as you're writing your own.

Significance

This proposal includes most of the significance information in the first few pages.

From NIAAA sponsored project 1R01AA021136-01A1 A RANDOMIZED
CLINICAL TRIAL OF CULTURALLY TAILORED MI

The proposed **R01** research, in response to PA 10-100, "Alcohol Use Disorders: Treatment, Services Research, and Recovery'', addresses the PA priority: Treatment for Health Disparities/Special Populations. Latinos, the largest and fastest growing ethnic group in the United States (U.S.), representing 14% of the population (1), are expected to grow to nearly 29% of the population by 2050 [2-3]. Like many immigrant groups adapting to U.S. culture, Latinos adopt the health behaviors of the mainstream population, such as hazardous drinking [4-6]. Hazardous drinking is a pattern of drinking associated with increased alcohol related problems: injuries, violence, sexually transmitted diseases [7-15], and increased risk for developing an alcohol use disorder (abuse or dependence) [7, 10. 16]. Latinos report a disproportionately greater burden of illness, injuries, workplace and legal problems [17-21] as a result of their alcohol consumption than other racial ethnic groups, including an elevated risk for alcohol-involved motor vehicle crashes and fatalities [20,22].

Early intervention prevents the need for more costly and complex alcohol treatment [23]. According to the National Academy of Sciences, dissemination of empirically-based interventions that are culturally tailored is particularly needed among Latinos [23-24] because they suffer alcohol-related health disparities [18-20, 25-26] and because alcohol treatment utilization rates are lower among Latinos than among other minority racial/ethnic groups or Whites [27-29]. Although evidence suggests that culturally tailored addiction treatment improves retention and treatment outcomes [30-31], progress in the field has been limited by the lack of prospective clinical trials comparing tailored to non-tailored treatment [23]. **The PI's (New Investigator) funded K award (AA014905) provided important pilot data demonstrating that culturally tailored motivational interviewing (CTMI) outperformed un-tailored motivational interviewing (MI). This study will be the basis for the current proposed study which is a larger scale version of the pilot.**

This example includes the significance sections for each aim just before discussing the method used for that aim:

From NIA sponsored project 1R01AG041955-01A1 Understanding How Personal Networks Change

Beginning of proposal:

1. Significance

Personal networks affect individuals' physical and mental health. (For overviews see, e.g., Cohen and Janicki-Deverts., 2009; Christakis and Fowler, 2009; Berkman; 1995; Berkman et al., 2000; Schwartzer and Leppin, 1992.) In our era of "networked individualism" (Rainie and Wellman, 2012), forming and managing social support relationships become yet more important. Semi-independent young adulthood lasts longer and is less structured (Settersten, et al., 2004; Arnett, 2006; Smith, 2009). Older people have fewer children upon whom to rely. (In 1985, the average 50-year-old woman had about 3. 2 children; in 2005, about 2. 0 children.1) Rates of living alone have soared, creating greater reliance on friendships (Klinenberg, 2012). *Yet we know comparatively little about how the networks change over time, respond to life events, and are reconstructed by individuals so as to sustain the support and better health that they provide.* We know little because (as explained below) we lack the critical data-set that includes: (a) full, in depth, multifaceted measures of individuals' personal, networks; (b) taken repeatedly over time so as to track change; (c) in a large and critical sample of Americans; and (d) with accompanying health measures. This project will precisely fill the need by gathering and analyzing the missing data. It uses the reliable, extended name-eliciting technique, focuses on two critical age groups in transition, interviews them three times, and connects network changes to health outcomes.

The significance of this project is delivery of the first panel data on how networks change in fluid life circumstances, and detailed analyses about these transitions. The results will answer longstanding questions about whether and how networks

affect general health. Understanding these processes would allow practitioners, and family and friends, to better anticipate ways to avoid unmet needs resulting from disconnectedness and insufficient ties, especially at critical life events, and to design better interventions. Social and health policies could incorporate an understanding of the importance of social relations and which social relations in particular affect health.

From the Approach section:

3. Approach

3a. Aim 1: Measure the main trends and variations in personal network change.

3a. 1. Introduction….

3a. 2 Justification and Feasibility. <u>Designs for Studying Personal Networks.</u> *A preliminary consideration that needs addressing is the choice to study personal, egocentric networks rather than whole, group networks.* Since its post-war emergence, social network analysis (SNA) has entailed two distinct approaches. One, originating in the anthropological tradition (e.g., Mitchell, 1969; Boissevain, 1974), involves mapping the multidimensional, egocentric networks of individuals (e.g., early studies such as Laumann, 1973; Wellman, 1979). The other, largely in the organizational literature, involves mapping specific ties in a closed population – such as trust in an organization (e.g. , Lusher et al., 2012), scientists' citations in a discipline (e.g., Brieger, 1976), or STD transmission in a school (Bearman et al., 2004). *Each approach is suited to answer different questions.* The egocentric approach addresses the influence of SNA on individuals, for example, how they find jobs (e.g., Fernandez and Weinberg, 1997.), decide to vote (e.g., Knoke, 1990), or find help (the social support literature). The "whole network" approach addresses, for example, group cleavages, diffusion of information, and inter-organizational relations. *The questions of this study, especially those of interest to health researchers, clearly call for the egocentric rather than whole network approach.*

Moreover, trying to extend egocentric networks out even to the first degree would yield a sample that, almost by definition, is not representative of the population, loaded as it would be with people who are highly likely to be connected (see Feld, 1991). Moreover, the total network approach necessarily censors those outside the closed group, whereas the ego-centric approach has no boundaries to limit the participation of alters.

A different concern, for both SNA approaches, is the accuracy of respondents' reports. In the ideal study, each key relationship's described by a respondent would be cross-checked with the alter. A few studies have done this on small samples (initially, Katz and Lazarsfeld, 1955; Laumann, 1973) and have revealed the scale and type of errors (e.g., people are good reporters of their friends' ages but not their politics). Doing cross-checks for a study such as this would be immensely difficult and make only a small sample affordable – for relatively little payoff. A half-century on, we have a good sense of where the errors lie. Moreover, the in-depth name-eliciting procedure used here yields greater reliability than the typical shortform or single name-eliciting question method used in the literature (McCallister and Fischer, 1978; Killworth et al., 1990; van Sonderon et al., 1990; van Groenou , et al., 1990).

Networks and Health. I*ndividuals' personal ties affect their physical and mental health, and quality of life* (reviews include: Pinquart and Duberstein, 2010; Cohen and Janicki-Deverts, 2009; Christakis and Fowler, 2009; Berkman; 1995; Berkman et al., 2000; Schwartzer and Leppin, 1992; illustrative studies include Maulik et al., 2011).

Support networks affect health through various channels -- by providing practical help and advice, modeling good health behavior, social control (e.g., shaming smokers), affirming the individuals' sense of mastery, making the person feel appreciated, and even unconscious physiological responses to others' presence (see, e.g., Berkman, 1995; Berkman et al., 2000 ; and Umberson et al., 2010 for reviews). Several studies (e.g., Kessler, 1992; Cornwell and Waite, 2009) suggest that feeling that one has support may be most important. Underappreciated is the finding that sometimes personal networks undermine health by, for example, modeling bad

habits or creating great stress (see, e.g., Rook, 1984, 1992; Antonucci et al., 1998; Rafaeli and Gleason, 2009; cf. Durden et al, 2007). *Thus, exactly how much and through what means networks affect health remain uncertain* (Thoits, 1995; Uchino, 2009; Christakis and Fowler, 2009; Umberson et al., 2010). *Largely missing in this literature is understanding the details of how change, under what circumstances, and with what consequences.*

Three factors in the existing literature contribute to these uncertainties: (1) Studies' reliance on summary measures of networks. Some, for example, ask respondents to estimate how many friends they have; they see their adult children without specifying which child; others how much support they feel they have (e.g., Sarason et al., 1983). *(2) Most network studies are cross-sectional* or for other reasons cannot disentangle cause and effect. For instance, some studies show, in contrast to the usual findings, that the less healthy have larger networks than the more healthy. This may result from the ailing reaching out more because they are needier. *(3) Studies with deeper measures or panel designs are of small and/or specialized samples* (e.g., Morgan et al., 1997a, b).

Existing Panel Studies are Insufficient. Reviewers will be familiar with some panel studies of personal networks. They largely divide into two types: (a) comprehensive inventories of individuals' networks for small and/or special populations (e.g., Adams and Torr, 1998; Degenne and Lebeaux, 2005; van Duijn et al., 1999; Morgan et al., 1997a; Terhell et al., 2007; van Tilburg, 1992; Wellman et al., 1997); (b), large-scale studies using quite constrained measures of social ties (e.g., Barnes et al., 2004; Bosse et al., 1993; Gibney and McGovern, 2012; Kaufman and Uhlenberg, 1998; Magdol and Bessel, 2003; Krause, 1999; Mendes de Leon et al., 2001; Menec, 2003 ; Maulik et al., 2009, 2011 ; Shaw et al., 2007; Chen and Silverstein, 2000; Silverstein et al., 2006; Thomas, 2011; Unger et al., 1999; van Baarsen, 2001). The larger studies typically ask respondents to rate their relationships – asking, for example, how often respondents see their relatives, or how satisfied they are with their social support. Rarely do they actually map the personal networks. One 17-year Dutch panel survey of 3000 respondents is an exception

(see Huisman et al., 2011, and for illustrative reports, Van Tilburg, 1998; Terhell et al., 2007). While providing some useful leads its limitations include a methodology that elicits names from of "domains" rather than names based on support and being limited to an elderly population. [2]

On-going, large-scale, longitudinal American data-sets include network measures, but they have their own limits, largely being limited to a few summary measures:

[List of studies and the measures they created]

These major, longitudinal data-sets can at best provide only partial network measurements, simply because they devote only a few minutes of their interviews (or just a page or two of their paper-and-pencil questionnaires) to measuring networks. Most get only summary assessments. The two name-eliciting questions used in NSHAP and SHARE are an advance but still provide partial glimpses rather than full maps of networks. Moreover, the **rationale** for this proposed study is that *none of the data sets mentioned here was designed with the goals of this project, to assess network dynamics and their consequences during rapidly changing developmental periods.*

Section 2: Innovation

As with the significance sections, innovation is often most effective if woven into various components of a social and behavioral science proposal. Innovation can be anything that your research will do that will either add to knowledge in the field, refine or develop new methods, change clinical or public health practice, or shed light on a given policy issue. Innovation can be highlighted in Significance, Approach and Impact sections or be included in its own section.

You should use the Innovation section of your Research Strategy to explain the following, according to NIH:

- How your proposal challenges and seeks to alter current research and clinical practice standards.
- Any new theoretical concepts, approaches or methodologies; instrumentation or interventions you plan to develop or use; and how these are better than existing methodologies, instrumentation or interventions.
- Refinements, improvements or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

In addition, NIAID advises applicants to be careful with this section. Demonstrating how your work is new and unique and how it will add significantly to what is known is sufficient evidence of innovation, the institute states in its online Research Plan Tutorial and Flowchart. If your proposal involves highly innovative approaches, on the other hand, you must build a strong case to challenge current models and your reasons for doing so.

At the same time, NCI recommends that your Innovation section should be no longer than a page and include the following:

- why your proposal's concepts and methodology are new to your research field
- how your study design and outcomes are new
- any novel findings from preliminary data you will detail in the Approach section

Therefore, to show your project's pioneering nature, you should present it in the context of what is already known regarding your field and what the challenges are. You can accomplish this with a brief, concise background section. And then you can clearly state what is new and groundbreaking about your proposal.

Do not make the reviewer guess where the novelty is, and do not be afraid to use the word "innovative." For example, consider the following:

This work is innovative because most existing studies simply document the availability of social networks and assume that these networks can assist people to find resources while this proposed study looks carefully at how characteristics of network members and the nature of the networks influence the kinds of resources available and the effectiveness of those resources in helping transitioning youth with ASD successfully enter adult services that meet their needs.

And although NIH presents three bullet points in its directions for the Innovation, you do not need to make each a subhead and address them individually in your application, reviewers say. The bullet points are good guidelines, and if you cover them all, you can be confident that you have a thorough Innovation section. But do not organize your information by bullets or subheads. Rather, provide a narrative that demonstrates you have thought about the pioneering nature of what you are proposing and that you have considered how your approach is different from others. In fact, some reviewers recommend that your Innovation section should be no longer than a paragraph or two.

Be aware that some reviewers will focus their attention on the techniques you use — to the virtual exclusion of other considerations. There is still a way   to emphasize the innovative components of your application if your work is based upon applying established techniques in a groundbreaking way to solve an important challenge. Namely, describe the endpoint of your research, if they work as planned, and then explain what is new and novel about the information you will have at the end of your project.

If you have been truly novel in applying established techniques, you will have a unique set of data that addresses a previously unanswered question — and therein lies your innovation.

At the same time, your proposal must be feasible, which means being too creative can present challenges for reviewers because they are established investigators. They

STRATEGY:

Describe the endpoint of your research, if they work as planned, and then explain what is new and novel about the information you will have at the end of your project.

have an eye for what they feel will not work, which makes them somewhat skeptical if your research is too creative, some reviewers say.

There are essentially two ways to address this:

1. Data — The data you present in your Preliminary Data section can convince reviewers. As part of that section, you should not only present the data, but also explain what you feel it means.

2. Track record — Your personal history as a research scientist is also vitally important to show that you know what you are doing regarding a highly innovative approach within your research. Your published works, employment history, education — essentially anything that allows you to demonstrate that you can think outside the proverbial box.

How your reviewers respond to your Innovation section typically involves how deeply they have read in their own research fields, how broadly their knowledge extends into other fields, and how much novelty and risk they are willing to tolerate. Historically, however, reviewers are mostly conservative and often do not support work at the earlier, potentially more pioneering stages. Consequently, if your proposal involves decidedly groundbreaking work, you might consider an R21 grant instead of an R01 so you can establish preliminary data (if it is currently unavailable) before moving forward with an R01.

Review This Example

Here are examples of Innovation sections in social and behavioral science proposals:

As quoted in full earlier, the Understanding Social Networks Study uses discussion of significance to show how the proposed study is innovative:

*3a. 1. **Introduction.** Using in-depth and broad name-eliciting techniques, the objective of Aim 1 is to map, at three waves, the personal networks of two respondent populations – 21-to-30-year-olds and 50-to-70- year-olds – undergoing major developmental changes.* This strategy will yield unprecedented information about the dynamics of social support networks. To appreciate the need for and the innovation of the proposed project, we briefly review (a) how Important personal networks are to physical and mental health, and (b) how current studies of network dynamics and consequences are limited by the nature of their samples and, more, by their network measurement approaches. We then proceed to explain the research design and measurement procedures that meet the need and the expected fruit of the research.

Earlier in the proposal, innovation is briefly described for the proposal overall:

Many panel studies measure social ties, but they use either (a) comprehensive inventories of personal networks for small, special populations such as recent widows, or (b) shallow measures of networks in large samples (for details and citations, see p. 3-4 below.) Network questions in the second type of studies typically get respondents' summaries of their relationships - e. g., how satisfied they are with their social support – rather than map respondents' networks. This project will innovate by applying for the first time (at least In U.S. samples) *a rich name-eliciting method tor describing personal network change in a panel.* The resulting data will permit analyses of network change at both the ego/network level (n > 1,000) and at the dyadic tie level (n>10,000). Moreover, the panel structure will permit causal analysis of detailed network data in a large and representative sample for effectively the first time.

In addition, the project will provide methodological contributions: (i) assessment of the reliability and validity of name-eliciting techniques in a large panel study; (ii) comparison of face-to-face and web-based applications of the full name-eliciting methodology; (iii) cost-efficient techniques for the rich description of networks.

NHLBI sponsored project 1R01HL114432-01A1 DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES?, outlines innovation in section 2 of the proposal:

Innovation: The proposed study would be the first large-scale, national observational study of parks to investigate the issue of health disparities in physical activity in public parks. Most national studies use existing databases that are often inaccurate or incomplete, and may not reflect what is happening in a given park or park system [29]. The recently developed System for Observing Parks and Recreation in Communities (SOPARC) is an innovative method for objective measurement of physical activity in parks and their contextual characteristics, including setting, facilities, programming and activities. This research will quantify – for the first time – differences in park characteristics and management practices and their effect on park use and physical activity in a large, national sample of high and low-income neighborhood parks.

Little is currently known about whether and how park management practices and characteristics affect park use and physical activity across different settings (geography, temperature) and different population subgroups, by gender, age group, race/ ethnicity and SES. Understanding these differences is essential to successfully promoting park use and physical activity across different geographic regions, climates, and demographic subgroups- and thus in the population as a whole. Identifying the park practices and characteristics that are most important for attracting racial/ethnic minorities to parks and supporting their engagement in physical activity would be an important step toward the public health priority of eliminating racial/ethnic disparities in obesity and physical health (30]. For example, the prevalence of obesity-related medical conditions such as diabetes is disproportionately higher among racial/ethnic minorities than non Hispanic whites [31]. In addition, research has shown that some park characteristics are more popular with females or males (32] and with African Americans compared with whites [33].

Engaging local citizens as "citizen scientists" in data collection will help to create an infrastructure that supports and sustains continuous quality improvement efforts in park management. We will train park professionals and members of community-based organizations (CBOs) affiliated with neighborhood parks to use SOPARC. Successful use of citizen scientists to complete data collection on a large scale has been demonstrated in ornithology [34]. The citizen scientists we will train will be armed with objective data to use in the democratic process and will share finding with elected officials and public servants. By including local citizens as active study participants, we also seek to motivate their ongoing involvement in the park improvement process after the proposed study is completed. By learning how to conduct SOPARC, they will have a sustainable way to monitor park use and physical activity.

In sum, *the proposed study will advance science and public policy on parks and physical activity and related health disparities. It will exert an enduring beneficial influence on the capacity of local citizens to assess the use and effects of parks over time. And it will establish a framework and a methodology for systematically studying the effects of future interventions designed to reduce health disparities and promote physical activity by improving parks.*

Social and Behavioral Science Methods in R01 Proposals

Methods available to social and behavioral scientists vary widely and include a range of qualitative and quantitative methods. NIH also supports studies that combine social and behavioral science methods with a wide array of clinical or biomedical methods. While a wide spread belief still exists that NIH reviewers prefer quantitative methods or methods that rely on hypothesis testing, the senior scientists, peer reviewers, and program officers interviewed for this report all stressed that NIH funds projects with both qualitative and quantitative methods. In fact, reviewers may suggest that quantitative studies add qualitative components. Mixed methods proposals are especially encouraged at present. Several program officers stated that purely qualitative studies may have a harder time getting funded in the current climate with its emphasis on measurable outcomes, but mixed methods studies would be welcomed. In fact, most of the study examples used in this guide use a mix of methods.

NIH has developed best practices guidelines on both qualitative and mixed methods research in recent years. The following are direct quotes from *Best Practices for Mixed Methods in the Health Sciences[3]*.

> **Mixed methods research in the health sciences:** A priority exists in health science research to develop new methodologies to improve the quality and scientific power of data that is leading to an extraordinary surge in methodological diversity. This diversity reflects the nature of the problems facing public health, such as disparities among populations, age groups, ethnicities, and cultures; poor adherence to treatment thought to be effective;

[3]See Creswell, J, Klassen, AC, Plano Clark, V, Smith, K . (2012). *Best Practices for Mixed Methods Research in the Health Sciences.* Washington D.C.: National Institutes of Health, Office of Behavioral and Social Sciences Research. Retrieved from http://obssr.od.nih.gov/mixed_methods_research/index.aspx

National Institutes of Health, Office of Behavioral and Social Sciences Research. (2001). *Qualitative methods in health research: Opportunities and considerations in application and review.* Washington D.C.: Author. Retrieved from http://obssr.od.nih.gov/pdf/Qualitative.PDF.

Plano Clark, V. L. (2010). The adoption and practice of mixed methods: U.S. trends in federally funded health-related research. *Qualitative Inquiry,* 16(6), 428-440.

Pasick, R. J., Burke, N. J., Barker, J. C., Galen, J., Bird, J. A., Otero-Sabogal, R., et al. (2009). Behavioral theory in a diverse society: Like a compass on Mars. *Health Education Behavior*, 36(5), 11S-35S.

behavioral factors contributing to disability and health; and translational needs for health research. The diversity also signals a growing acceptance of qualitative and social science research, the formation of interdisciplinary research teams, and use of multi-level approaches to investigate complicated health problems, such as the patient's point of view and cultural and social models of illness and health.

Contributing to this interest has been the increased methodological sophistication of mixed methods research in the social and behavioral sciences. NIH-funded investigators are using research approaches, such as in-depth interviews, field observations, and patient records to understand individual experiences, participant involvement in interventions, and barriers to and facilitators of treatment. These approaches often are combined with clinical trials, surveys of attitudes and beliefs, and the epidemiological measures to better understand health problems (Plano Clark, 2010). (p2)

A definition: Many definitions of mixed methods are available in the literature (e.g., see Johnson, Onwuegbuzie, & Turner, 2007). For purposes of this discussion, mixed methods research will be defined as a research approach or methodology:

- focusing on research questions that call for real-life contextual understandings, multi-level perspectives, and cultural influences;
- employing rigorous quantitative research assessing magnitude and frequency of constructs and rigorous qualitative research exploring the meaning and understanding of constructs;
- utilizing multiple methods (e.g., intervention trials and in-depth interviews);
- intentionally integrating or combining these methods to draw on the strengths of each; and
- framing the investigation within philosophical and theoretical positions. (p4)

The combination of quantitative and qualitative data: Mixed methods research begins with the assumption that investigators, in understanding the social and health worlds, gather evidence based on the nature of the question and theoretical orientation. Social inquiry is targeted toward various sources and many levels that influence a given problem (e.g., policies, organizations, family, individual). Quantitative (mainly deductive) methods are ideal for measuring pervasiveness of "known" phenomena and central patterns of association, including inferences of causality. Qualitative (mainly inductive) methods allow for identification of previously unknown processes, explanations of why and how phenomena occur, and the range of their effects (Pasick et al., 2009). Mixed methods research, then, is more than simply collecting qualitative data from interviews, or collecting multiple forms of qualitative evidence (e.g., observations and interviews) or multiple types of quantitative evidence (e.g., surveys and diagnostic tests). It involves the intentional collection of both quantitative and qualitative data and the combination of the strengths of each to answer research questions.

The integration of multiple forms of data: In mixed methods studies, investigators intentionally integrate or combine quantitative and qualitative data rather than keeping them separate. The basic concept is that integration of quantitative and qualitative data maximizes the strengths and minimizes the weaknesses of each type of data. This idea of integration separates current views of mixed methods from older perspectives in which investigators collected both forms of data, but kept them separate or casually combined them rather than using systematic integrative procedures. One of the most difficult challenges is how to integrate different forms of data. (p5)

Mixed methods research can be done in an almost infinite variety of ways. As this NIH guide suggests, it involves not simply adding a minor qualitative component to a quantitative study, but truly integrating the various methods used. At NIH, researchers are encouraged to reach across the divide between biomedical, social science and clinical research in designing their studies. Your goal in an R01

application is to choose the best methods to explore your research question, assemble a team that can effectively carry out an interdisciplinary, multi-methods framework, and prove to reviewers that this methodological strategy is an innovative and effective way to achieve the specific aims stated in your proposal.

Figure 3: General Strategies for Developing a Mixed Method Project

- **Specific methods will depend on the research question, available data, and sponsor requested outcomes.**

- **Quantitative, clinical, and qualitative components should be conceptualized together.**

- **Different research strategies should be employed at different times throughout the project to build on findings from earlier results.**

- **Analysis should incorporate all data from all methods equally but different methods may be used sequentially, with preliminary analysis used to develop instruments or samples for components using other methods.**

- **The mix of methods will vary according to each research question, but methods should be selected that will best identify general patterns or test results AND provide the qualitative data to explain why patterns occur.**

By their nature, multi-disciplinary projects involve several co-PIs, and often clinicians or other practitioners. Developing a proposal will take a long time because you need to assemble your team before beginning proposal writing and work together to determine the best mix of methods for your approach to your research question. Writing the proposal should involve various team members drafting sections based on their expertise, one person pulling all of it together and then time for comments from all contributors before it is finalized. One experienced researcher suggested reserving at least six months to develop a multi-methods proposal.

Figures four and five lists some of the potential methods that can be used in an NIH funded project. Further discussion on these methods is available from a variety of sources. Many of these are summarized in the Principal Investigators Association guides on multi-methods research design and interdisciplinary team projects. The methods listed in these two figures are only a few of the potential methods that can be used in an R01 project. In order to explore a wider range of methods that may be appropriate for your study, it is helpful to do some research using NIH reporter http://projectreporter.nih.gov to find projects that address similar kinds of questions. Noting the methods each project uses may be a good place to start in developing the appropriate methods for your project.

If you choose methods that you have not used in the past, it would be important to add a member to your team as a co-PI or consultant who has expertise in those methods. Perhaps the biggest challenge in developing an R01 proposal, regardless of whether you are using a single method or multi-methods, is to explain those methods succinctly to an audience which is likely to include readers who may have no familiarity with those methods. Senior researchers and program officers recommend several strategies to explain your methods given the page limits of an R01 proposal. These include citing methods literature from a highly respected source that explains the methods in detail and providing a short paragraph to explain each method in plain language. It is also helpful to include copies of survey instruments, interview guides, or other data collection tools as appendices. However, be warned that reviewers may not read your appendices.

Figure 4: Types of Methods for Mixed Methods Projects

Qualitative Methods

- **Participant observation**

- **Depth or life history interviews**

- **Key informant interviews**

- **Focus groups**

- **Document analysis**

    > **Organizational materials**

    > **Budget data**

    > **Historical data (board minutes, newspaper articles, etc.)**

Quantitative Methods

- **Analysis of Government surveys and data (Census, BLS, Health Department, Welfare, etc.)**

- **Survey research**

- **Experimental design**

- **GIS mapping analysis**

Network Analysis

- **Analysis of social networks:**

    > **Quantitative – coded data on connections that is mapped using network software**

    > **Qualitative – subject reports of connections, frequency of use, when and why used**

Modeling and Systems Analysis

- **Decision modeling**

- **Dashboard modeling**

- **System dynamics**

---

[4]See Multi-methods Research Design for Applied and Translational Projects: A Guide for Health, Human Services and Population Science Researchers https://principalinvestigators.org/product/multi-methods-research-design-for-applied-and-translational-projects-guide/ for more information on developing multimethods proposals and Interdisciplinary Research Teams: The Scientist's Guide to Building Strong, Productive Teams https://principalinvestigators.org/product/interdisciplinary-research-teams-guide/ for more detailed information about carrying out multi-methods projects.

Figure 5: Applied Clinical Methods in Multi-Methods Studies

Applied clinical methods refers to any medical or psychological test, data from medical, education, human services program case files, or medical procedures that provides data relevant to the research project.

- **Health and rehabilitation studies:** Any form of medical tests, obesity and nutrition measures, or review of medical records. Medical results from clinical drug studies or evaluations of clinical effects of using a new device or medical protocol for care.

- **Population or public health:** Similar measures to health studies, administrative data from clinics or government entities on numbers of people screened and screening results. Incident reports for illness, violence, etc.

- **Social or human services:** Practice notes on program participants, case file reviews or outcomes measures from programs.

- **Mental health, social or human services, vocational rehabilitation:** Results from physical or psychological testing

- **Health, public health, social services or educational communications:** Outcomes measures for interventions or pre-test/post-test data

- **Educational research (psycho-educational issues, children with disabilities, impact of health disparities on education, etc.):** Educational tests, grades, and other achievement measures

If you are using methods that are not often seen in previous NIH proposals, you may want to state in your cover letter which methods you plan to use. That way, NIH's Center for Scientific Review staff can find reviewers with expertise in those methods. That said, not everyone on the review panel or even the team of three reviewers that handle your application may have any past knowledge of some of the methods you plan to use. For this reason, your methods sections should clearly explain your methods in language understandable by an educated lay person with no expertise in your field. Remember, pretend you are explaining your project to your dentist.

Whichever methods you choose should be the best combination of research strategies to address your research question and all you to succeed in your Specific Aims. The key to a successful proposal is not using novel methods for the sake of innovation alone. Methods are justified because they are the best tools to address each aim. As you think about which method to use remember that the goal of your approaches section is not just to talk about how you plan to do your research, but explain why these methods are the best strategy to achieve your goals. As one senior researcher and peer reviewer with expertise in qualitative and mixed-methods commented:

> *It is Important to do research in stages, starting with observation, then propose questions [for interviews and survey], than collect data using the standard questions [used in nationally normed questionnaires on the research topic] and ask study participants what they think about those questions. I like to let the data [collected through various methods] fight itself out. Throw in standard questionnaires, various methods. Get as much different kinds of data as possible and then triangulate [the results to understand the problem].*

Section 3: Approach

The Approach section is the heart of your Research Strategy. This is where you will provide the details of your research to convince reviewers that you understand what the work entails and have the resources and expertise to conduct the research.

According to NIH, you should use this section to detail the following:

• Your overall strategy, methodology and analyses you plan to use to accomplish your specific aims. And if you have not included a separate resource-sharing plan, you should use this section to indicate how you will collect, analyze and interpret data, as well as any resource-sharing plans as appropriate.

- Potential challenges, alternative strategies and benchmarks for success that you anticipate to achieve your aims.

- If your project is in the early development stages, note any strategies to establish feasibility and how you plan to manage any high-risk aspects.

- Any hazardous procedures or situations and precautions you will use to address them.

NIAID further recommends that you follow these strategies for this section:

- Describe the research for each Specific Aim.

- Define the potential next steps for the aims, but do not describe them in detail. This may lend itself to a flowchart or decision tree where you can indicate that if you get result X, then you will follow plan X, but if you get result Y, you will follow plan Y.

- Provide enough preliminary detail to demonstrate to reviewers that you understand what your proposal involves and can effectively conduct the research.

  o If you are a more experienced investigator, cite relevant work to show your expertise.

  o If you are a new investigator, indicate you can handle the methods you intend to use, and particularly point out if you have used it before. If you have, cite it, and skip the description.

  o If you lack the expertise to accomplish the work, point out colleagues who do. Their Biosketches should highlight experience that supports their roles on your application.

  o Outline your methods in less detail than you would in a publication. Provide more detail for unique or new methods, and keep graphics simple because they are clearer and can save space.

- Explain methods to which you bring a unique ability.

  o If some of your methods are ordinary or contracted out, focus instead on those that you bring something unique to and that are interesting.

  o Next, describe your strategy, showing subsequent research based upon the results.

- o Draw connections between your personal statement and other Biosketch information, highlighting what you are doing that's different and what you do well.
- Incorporate milestones and timelines, assessing whether they are appropriate as you write.
- If you do not need the information to support your case, leave it out of the Approach section. Reviewers will look for flaws and heavily penalize you for them. So do not give them ammunition by including anything you feel you do not need.
- Include a timetable showing how and when you will accomplish your Specific Aims, noting any overlap of experiments and alternative paths.

NCI also suggests that your Approach include the following additional details:

- For early-stage projects, your strategy to establish feasibility and address high-risk aspect management
- New methodologies used and why you feel they are an improvement.

Further, NCI notes that you should number your Approach sections to correspond to your Specific Aims numbers. And you may include the preliminary data or progress report before the Specific Aims or integrate the data/report as part of your methods description for each aim.

The Institute also recommends that you avoid excessive methods detail by referring to publications that describe your methods. Keep in mind that any publications you cite should be your own if possible. And indicate why you will use one approach or method (if applicable) — and include the "how" and the "why" — rather than others because this will demonstrate that you simply did not overlook any alternatives. If you are using a complex method for the first time, be sure to demonstrate your familiarity with the methods techniques and potential challenges. If necessary, add a co-investigator or consultant who is familiar with the method.

If your application involves proposed collaborations, document this with letters from the individuals involved, NCI says.

Allow Enough Time

Because the Approach is so central to your Research Strategy section, you will spend most of your proposal-writing time on it. And it is what reviewers will spend most of their time evaluating. They will be especially careful to scrutinize it for potential problems, alternative strategies and benchmarks for success.

REMEMBER:

Reviewers will be especially careful to scrutinize the Approach for potential problems, alternative strategies and benchmarks for success.

NIH's Office of Extramural Research looked at the five key criteria – Approach, Significance, Innovation, Investigators and Environment — and how well scores for each correlated statistically with an applicant's Overall Impact score. Based upon this analysis, the Approach score turned out to be the best predictor of the final impact score, with a correlation coefficient of 0.82.

The Approach section is also where many new principal investigators make one or more of the standard errors that are relatively easy to identify and describe. If this is the case, your Summary Statement may include such stock critiques as the following:

- The applicant is overly ambitious
- One or more aims are unfocused or underdeveloped
- An aim is just a fishing expedition
- There is too little description of results analysis
- The applicant over-relies on a preferred hypothesis
- An aim is just too risky.
- The applicant does not allow enough time to complete the project or have enough personnel identified in the budget and project team to achieve it goals.

Allotting enough time, people and money to do a project is a particular problem for social and behavioral science proposals. Applications usually include a timeline in the Approach section that maps the various components of the project and the time line for carrying it out. Established investigators usually know how long it takes to complete a project, but this may be less true of early investigators. One long-

term research methods instructor tells students to budget how long they think each component of a project will take, and then double that amount of time. With projects that require developing samples from several sources, the amount of time needed to develop a large enough sample that meets your criteria may be double what you planned.

Likewise, reviewers will look at your description of the team, budget, and budget justification to ensure that you have enough people to do your project and that they have the expertise to do the work. This starts with identifying the team of key researchers involved in the project and developing a budget that includes enough time for each person to carry out their part of the project. The actual activities and effort needed by each individual will be discussed in the Budget Justification. Just as important, do you have enough research assistants or other mechanisms to collect social science data directly from participants? Social science projects, particularly qualitative methods, can be costly because of the need to hire interviewers and allow enough time for them to schedule (and often reschedule) interviews or observations and complete the data collection. Survey data can be collected through contracts with university or private sector survey collection departments or organizations. For both qualitative and quantitative data collection that involves multiple sites or interviews, social and behavioral scientists also specially train students or community members to help conduct the research. Students in courses may be involved in a project as a service learning project, or conducting research for credit as opposed to direct payment. Community members trained as researchers could come from a variety of sources and either conduct research for pay or as part of participation in an organizational activity as a volunteer.

For example, the study of parks and physical activity plans to use "citizen scientists," people from the community specially trained by the research team to carry out part of the project.   This kind of action research has a long history and is an approach that has been funded by some Institutes and Centers at NIH in the past. Proposal reviewers needed to have enough information about the method and the experience of the research team in using it in the past in order to decide if this was a sound method.

TIP:

Anticipating critiques during your proposal writing is one of the best defenses you have, and knowing that the Approach score provides the strongest correlation to your Overall Impact score shows that this section is where you should devote most of grant preparation time.

Reviewers may genuinely identify these flaws in a grant application, but they occasionally invoke them as a cover when they lack enthusiasm for a proposal and cannot precisely articulate why. Anticipating these critiques during your proposal writing is one of the best defenses you have, and knowing that the Approach score provides the strongest correlation to your Overall Impact score shows that this section is where you should devote most of grant preparation time.

Keep in mind that reviewers do not want to see details like a step-by-step discussion of how you plan to record observations. As one program officer commented:

> *The extent that the reviewer comes away thinking they have learned something about the topic and methods, gives them confidence that you have something to offer. [Reviewers will give your study a] more positive response if you can start with an interesting quote and [explain your approach] in way that is compelling. Make an effort to write grounding, foundational, aims, with a clear statement about what level of knowledge exists that supports the methods and approach you are using. Explain the basics of your methods but do not get lost in them.*

What they are really interested in is your thought process regarding how you will accomplish each aim, including the following:

- Have you carefully thought through the problem you are trying to solve?
- Have you developed an adequate sampling frame and how do you plan to choose participants for your project?
- What is your initial plan of attack?
- How likely is that plan of attack to work?
- What are the possible things that could go wrong?

---

[5]See http://projectreporter.nih.gov/project_info_description.cfm?aid=8468334 and example below. Additional information on Participatory Action Research is available in PIA guide Participatory Action Research from A to Z: A Comprehensive Guide https://principalinvestigators.org/product/participatory-action-research-from-a-to-z-a-comprehensive-guide/

- What aspects of feasibility have you not yet demonstrated?
- What is your plan for dealing with those problems if the research does not go as planned?

To address the stock critiques above, some reviewers suggest that you spend a paragraph or two explaining the rationale of each aim, noting why you are doing it and outlining the research related to each one. You should also choose figures, tables or other visual data that allow reviewers to understand that you are the expert, careful and will do what you say you will.

A good approaches section links the design, methods, and analysis to each other. This can be done aim by aim or by explaining each aspect of the research (sampling frame, data collection method, analysis) through its relationship to the research question and overall impact you hope your project will have. For social and behavioral science proposals, it is also important to explain how the theory behind your research informs your methods and analysis. As one senior researcher commented:

> *The design section might be a really good place to introduce the theoretical frame. In design, a really powerful thing that social science can bring is that we can do theory and use it. That is one of those large criticisms of reviewers: method without theory. The extent that you describe your proposal as theory driven makes it far more competitive.*

Another key component involves describing the data you plan to use in your study. If the project will use data collected by someone else, from government statistics, to Medicaid data, to administrative data from public health departments, hospital or clinics, you will need to briefly describe what is in this data set and how it has the data to answer your research questions. Reviewers will want to know why this data set as opposed to others. If you are collecting your own data, explain the types of data you plan to collect, the time frame for data collection, and so forth. If you are doing an experimental design, what is the length of the experiment and what choices are you offering to people who are selected for the control group? Why did

you make the choices you made regarding what data set or collection method to use? Why is it better than other options?

Program officers and reviewers stress that it is very important to describe and justify your choices regarding your sample. How many people do you plan to interview if you are doing either survey or qualitative research? What are the characteristics of the sample? If you are doing survey research, how will you ensure that you have a representative sample? How many subjects do you need to include in your sample to determine statistical confidence? The Approach section needs to address the main categories of sample design, selection of subjects, attrition, and measures used to determine if the sample is representative.

Those using qualitative methods need to address the same categories: using language that is familiar to survey researchers. What is your unit of analysis? How will you select who to include in your study? How will you determine if the group of people you interview is representative of a larger population? Why would representativeness be important or unimportant given your methods?

Your discussion of methods should also outline the measures you plan to use to study your topic. This may include using well known normed instruments or creating new ones to meet a particular purpose. You may also use counts of public health data like incidences of cancer or obesity rates to measure if a particular policy strategy or intervention is working as planned. When referring to well-known measures, references to the key publications on those measures or sources for government data is sufficient – you do not need to describe these kinds of measures in detail. If you are creating new measures, it is helpful to have pilot data on that measure before using it in an R01. Questionnaires or other data collection devices for new surveys or measures should be included in the appendices.

You can also use your Approach section to provide details regarding novel aspects of your work. For instance, you plan to use a better, more innovative method of calculating sample size that reviewers likely will not recognize. Should you stick

with the more conventional sample-size calculations? Or put the more sophisticated method in an appendix?

Neither. Instead, you should reference a publication that explains the new method and provide a brief description of its advantages in your Approach. If you feel you need a larger explicative discussion, seek your review officer's permission to submit it as supplemental material once you have your study section assignment.

Your Approach section should also discuss potential problems you may have conducting your research and how you plan to address these issues should they occur. These include challenges collecting the data as well as analyzing it. This section should introduce actual limitations and potential flaws. This shows that you have thought through your research plan carefully. As one senior researcher noted, you should be "deeply thoughtful regarding the contingent nature of knowledge and how you are going to sort out your results."

Another key component often left out of an Approach section is a justification for your data and methods. What advantage does your method have over others? Reviewers will want to know that you did not just pick methods because others use them or your advisor invented a new approach, but because it is the best method or mix of methods to address your particular research question.

You will also want to tie the different areas of your application together to better support your proposal. For instance, if you are demonstrating the feasibility of recruiting a target sample size in a psychosocial treatment outcome study, you will want to discuss your ability to recruit a specific number of participants in both the Environment/Resources section and in your Approach. The ability to recruit adequate patient population is that crucial to clinical studies. In this case, you would use one sentence in the Approach to document annual patient accruals and/or past successes in recruiting patients, and then use the Environment section to provide slightly more detail regarding why your institution is such a good place to do the clinical research with access to your target study population.

In addition, for research that involves nonstandard, nontrivial "data analysis" needs, be sure to sufficiently describe those needs in your Approach because this will inspire reviewer confidence in your project. With the Research Plan's 12-page limit, you should use approximately a half-page for this or as much as a full page if your data analysis is particularly complex and integral to your success. If your project is a survey or clinical trial, for example, remember that NIH will assign statisticians to specifically evaluate the statistical design and power issues, which you must discuss in your Approach.

Example Proves Helpful

Consider the following sections from a successful grant application.

From NIA sponsored project 1R01AG041955-01A1 Understanding How Personal Networks Change:

3a. 3 Analytic Strategy to Meet Aim 1. Using in-depth and broad name-eliciting techniques, the project will map, at three waves, the personal networks of two respondent populations – 21-to-30-year-olds and 50-to-70-year-olds -undergoing major developmental changes.

- Target Populations. We focus on 21-to-30 year-olds and 50-to-70 year-olds because, they provide two concentrated populations undergoing especially substantial life changes - in activities, family status, residence, and so on -- with accompanying changes in social connections, albeit of strikingly different kinds. We use a narrower age range among the young because so much volatility exists in that decade; important life events are more stretched out over time at older ages so we use a 20-year range there.

The logic of this study does not require nationally representative samples, because we are not seeking to describe the universe; we are seeking to measure change in theoretically critical populations. We seek to accurately represent English-

and Spanish-speaking members of the two age groups in northern California. Nonetheless, some diversity of locales is important to assess robustness and test for variations. For cost-saving reasons, we stay in the northern California region. Any single region is, of course, unique in its own way. To the extent to which the region differs from many others, that difference is advantageous – its demographic, cultural, and economic diversity. (Despite popular impressions, the area is not particularly "odd" [Fischer, 1982: 268-71].) Samples will be drawn from three strata: urban centers (San Francisco-Oakland-San Jose); suburban areas around the cities; and small town and rural areas at least one hour's drive away. The region contains most of the demographic and cultural variation that needs to be captured. (Note: We intend to submit a competitive supplement to extend the sample in two directions. One is to oversample African-, and Asian-Americans. A second plan is to replicate the sampling design in another, quite different region - probably the South - in order to both expand generalizability and to explore regional-cultural differences.)

- Three Waves. We need three waves, 18 months apart, rather than only two in order to (a) *track the reconstruction of networks* due to change. We expect many respondents to experience between t(1) and t(2) certain network disruptions – e.g., loss of friends due to job move, death of parent – which will show up as "holes" at t(2). And we expect many of these respondents – which ones an being an important research question – to fill those holes, say someone to confide in, by t(3). Three waves is a minimum for detecting this sort of reconstruction. (b) Three waves are a statistical *minimum for disentangling real change from measurement error* (Wiley and Wiley, 1970; Alwin, 1997: Ch. 5). This is discussed further below (p. 10). Clearly, multiple waves would be ideal but this proposal at least lays the minimum groundwork for such analyses. The question arises as to whether 18 months is enough time to observe change. Focusing on age ranges with major life course transitions is meant to maximize such change; the calculation of life events (below) suggests there will be sufficient events; and finally, we keep open the possibility of extending the panel through supplementary grants. For some analyses, we can use the entire 36-month period between waves 1 and 3 to capture more change.

- • <u>Sampling and Recruitment:</u> *We will interview 21-to 30 year-olds and 50-to-70 year-olds in three waves, 18 months apart. We use mixed interview modes in an explicit experiment.* We draw from six contiguous counties in the San Francisco Bay area (San Francisco, Alameda, Marin, Contra Costa, Santa Clara, San Mateo), developing a multistage sampling frame, with clusters at the zip code or census tract/block levels (to be determined precisely in the first year of the project) designed to minimize sampling error and maximize cost and time efficiencies. The key problem in recruiting a sample population of young adults is their use of cell phones and the general difficulty in reaching them. Random-Digit-Dialing (RDD) has become less effective among all age groups, but this is especially so among the young. While a cell phone recruit approach might be considered appropriate for young adults and increasingly other age groups, especially in renter populations, it is important to note that the methodology for obtaining representative samples from a population consisting increasingly of cell phone only households is currently at the exploratory stage (Peytchev et al, 2010; Smyth et al., 2010). NCHS estimates in 2011 indicated that 48% of U. S. households have only cell phones or use their cell phones for the majority of calls (Blumberg and Luke, 2011). An added challenge to geographically based representative samples is the fact that a growing proportion of cell phone numbers, are owned by persons who have moved out of the area code but retained the number. Meanwhile, Address-Based-Sampling (ABS), which uses the US Postal Service Delivery Sequence File (DSF) and thus covers 98% of physical addresses, combined in some cases with identified telephone numbers, has become increasingly recommended for developing representative samples (see Link et al., 2008, 2011; Blumberg and Luke, 2011). Rather than using a dual frame sampling design of RDD and cell-phones (further complicated by the fact that some individuals have multiple land and/or cellphone lines), we will use the ABS methodology for both age groups in order to have consistency. Link et al. (2008) found that response rates in California were similar for RDD and an ABS mail method. ABS is also in a stage of rapid development: In his article on ABS, lannacchione (2011) wrote, "Read this article quickly. By the time you're finished, parts of it will likely be out of date. "(p. 556).

During the design phase of this project we will avail ourselves of the most recent experimental design research on this method through discussions with other survey practitioners, and work presented at annual conferences (e. g., American Statistical Association and the American Association of Public Opinion Research) in addition to the latest publications.

Letters will be sent to households on UC letterhead (following some experimentation). To increase response, we will also telephone a match of phone numbers for non-responders. The DSF file is purchased through vendors. (M and S) who can also provide addresses matched to household data, such as surnames, demographic information and SES data, sometimes at the address-level and sometimes at the block level. The surname enables a personalization of the envelope and greater response rate, and the appended. SES and demographic information provides greater efficiency in the sampling frame and facilitates evaluation of non-response error. People will be able to answer a postage-paid letter, visit a website to sign-up, or call a toll-free number for questions, which will also allow for recruitment. The website, hosted on a UC server, will contain information about the project. Households responding to the invitation to participate will be able to sign up more than one person with the knowledge that only one person will be selected per household, to be determined based on needs for sample disposition. After obtaining informed consent, appointments will be set-up by the data collection vendor for Wave 1 face-to-face interviews, or respondents will be emailed a link for the web-based survey. Previous research indicates this is a reasonable process but very few comparable designs have been tested (see Steiger et al, 2012 for a recent panel recruitment by Gallup). Respondents will receive a $25 incentive for the first wave, increasing to $30 and then $35 for the two subsequent waves of interviews. Between each wave, respondents will be contacted by either USPS or email, with additional effort undertaken to track migrating respondents in order to reduce attrition.

Recruitment, face-to-face interviews and panel maintenance will be carried out by Research Firm B located in San Francisco, allowing for ease of an ongoing working relationship during the data collection process and because of their expertise in mixed and multi-mode data collection, personal interviewing and hard-to-reach populations.

The web-based survey portion will be provided by RESEARCH COMPANY C in Santa Monica, CA, taking advantage of the software development for the SHARE study.

• Data collection: We begin with a total sample size of 1, 200 -- 600 for each age group. That number is based on the estimates of life events discussed above, expected attrition, and minimizing costs. In each planned location, representative samples of English- and Spanish-speaking respondents aged 21 to 30 and of 50 to 70 will be drawn. (Recent work suggests important differences between Hispanic respondents who answer in English versus Spanish - Lavrakas et al., 2011). This study is a multi-mode design, that is, at any given wave respondents will be split into different data collection modes, and also some respondents will take web survey after having completed a face-to-face survey in the previous mode. Each screened case would be randomly assigned to the face-to-face (FTF) or web condition (see Aim 4, below, for more explanation regarding this methodology). Those assigned to web surveys who are without web access or internet knowledge would be asked to do FTF, yielding three categories of respondents at t1: (a) FTF; (b) web; (c) assigned to the web but conducted FTF. Based on Pew data of online populations by age groups, getting a 75:25 distribution of FTF:web at t1 for the older sample would require initial sampling ratios of roughly 60:40.[6] Similar adjustments to the random assignments will be made in the next two waves to shift respondents from FTF to web. This method is a practical compromise to the ideal assignments. We can identify the cases in category (c), unable to use the web, and use that information in the models (Vannieuwenhuyze et al., 2010).

For each of three locales and each age group, there are three waves, 18 months apart, in the following patterns: (a) FTF-FTF-FTF; (b) FTF-FTF-Web;(c) FTF-web-web; (d) web-web-web. If we assume a roughly 10% attrition rate at each stage, then the table below summarizes the sample distributions.

APPROXIMATE NUMBER OF CASES (Split evenly by Age Group)

	Urban Centers			Suburban			Rural/Small Town		
	t(1)	*+ 18m*	*+ 36m*	*t(1)*	*+ 18m*	*+ 36m*	*t(1)*	*+ 18m*	*+ 36m*
FTF*	*300*	*180*	*80*	*300*	*180*	*80*	*300*	*180*	*80*
Web	*100*	*180*	*240*	*100*	*180*	*240*	*100*	*180*	*240*
Tot. N =	*400*	*360*	*320*	*400*	*360*	*320*	*400*	*360*	*320*

*FTF includes a percentage of those who are Research Company C only assigned to the web condition but cannot do it on the web. They will be tagged as such.

- The survey instrument will yield new, detailed, longitudinal data on individuals' personal support networks. Appendix A presents an initial draft of the screening survey instrument, and Appendix B contains the initial draft of the full questionnaire for wave 1. Much of the first year of this project is devoted to fully developing and testing this survey for use in two modes of data collection - face-to-face and web, and for two populations, older and younger persons. The usual demographic and background questions are, of course, included, most often adapted from the GSS to provide benchmarks. The key sections are:

- Personal Network Questions. We will and improve the name-eliciting technique from the Northern California Communities Study… (b) We will modify questions to insert *more explicitly health-related support and exchanges.* These modified name-eliciting questions are noted in Appendix B. Depending on time availability, we could add more questions about health behavior. (c) We will add *two distinctly new questions.* One specifically elicits *burdensome ties* (Rook, 1984). Another specifically asks about alters who are largely contacted via *email, internet, or social media.* (d) We will add, in waves 2 and 3 questions about people who were named in the previous wave

but not repeated and about people who appear for the first time. (e) We ask questions tapping respondents' *feelings toward their social lives* and how supported they feel. In particular, we use the NIH Comorbidity survey's items on how much respondents feel they can count on friends and relatives (Kessler et al., 2004).

The result will be *many measures of respondents ' networks* from simple ones like size and support to complex ones like density, homophily, reciprocity, and turnover rates, to name just a handful. They will be oriented to the health arena, but will also support inquiry into other aspects of network change, such as educational attainment, labor force participation, and social activities. Critically, the method also yields a second data-set, *measures of specific ties*, enabling dyadic analyses - looking at the patterns and consequences of, for example, ties that are homophilous or ties that are formed at school.

- Health Measures. We have borrowed or adapted a long set of health measures from HRS and to a lesser extent, ADD Health. They cover chronic and acute health conditions, including treatment regimens; functioning, such as the ability to walk well; health behaviors, such as smoking and exercise; depression (the K6 version of the CES-D depression – Kessler et al., 2002; Cole et al., 2004); and begins with the well-validated self-rating of health (Jylha, 2009; Benyamini, 2008).

- Personality. Personality differences shape social engagement. We will use an abbreviated form used by GSS and others of the standard "Big Five" personality scales (see John et al., 2008; Crede, et al., 2012). A version of the UCLA Loneliness scale provides a measure distinct from depression (see Hughes et al, 2004). We will use one of the classic measures of internal vs. external locus of control (sense of efficacy), which has been shown to have important social and health consequences (Gecas, 1989; Lefcourt, 1992: Gale et al., 2008). Finally, the GSS happiness item is a standard, brief measure of subjective well-being.

-

- Life Events Inventory. To avoid conflation, we must distinguish life events as "external shocks" in three categories: social events (marriage, divorce, new child, parental divorce or death, etc.), health events (e.g., accidents, illness), and largely independent events (e. g., job loss/gain, retirement, graduation, fire, incarceration of self or intimate). Some life events and life cycle transitions (such as union, marriage, and divorce) will be known in the normal course of re-interviewing. But we will present a checklist of important occurrences in respondents' lives between before and between interviews. … The 18-month windows enable us to capture both short-term responses and longer-term adjustments. Following Turner and Avison (1992), we will add two or three follow-up questions asking respondents which of these events affected them the most and whom, if anyone, did they turn to for support or celebration. We consider it critical to thoroughly pretest and pilot-test the instrument and have built that into the schedule. We plan to use 50 cases each of pilot tests on the FTF and the web format with diverse respondents.

- Modeling. Network data over time pose complex statistical issues. Specific ties are nested within waves and waves are nested within individuals (e.g. van Duijn et al., 1999). Also, several processes contribute to variance over time (e.g , Leik and Chalkley, 1997): secular development (i.e., aging - which can be period effects or growth curves); responses to exogenous "shocks" such as life events; random changes (labeled "brownian motion" by Leik and Chalkley, 1997); and measurement error. A third complication entails is handling causal sequences and recursive effects. Bollen and Brand (2010) recently addressed the complication that the effect of a time-invariant variable might vary by age or period. (We are exploring some of these issues in the WLS data; {Redacted – In Preparation.} Given the complexities, DR G, an expert in modeling change, will serve as our modeling consultant.

Aim 1 entails describing main trends and main variations in network change among specific populations undergoing major life-course developments. What are the main, developmental trajectories for various network dimensions - size, composition (e.g., percent kin, nonkin; local v. distant ties; context; duration) support and exchanges provided, density, stability, etc.? Examples of hypotheses:

- As older respondents age, mean network size declines, percent kin increases, density increases, sociability declines.
- There is less in the literature to suggest hypotheses for the young, but we might speculate, for example, that: (a) they have greater network turnover level the older do; (b) turnover declines over time; (c) ties with workers increase, and so on.

These are baseline trends. *Critical to the project is understanding variations in these trends.* We focus in particular on:

- Personal variations by age, gender, class, location, and ethnicity-race (where possible). For example, do, as cross-sectional and small studies suggest, women sustain intimate ties better than men do, and if so, which ties for which kinds of exchanges?
- Dyadic variations by context of relationship (family, work, neighborhood, etc.). If, for example, as we might expect, kin ties last longer from t(1) to t(3) than nonkin ties, which kin ties engaged in which activities? Perhaps young people turn less to parents for emotional support and more exclusively tor practical support.

From NCI sponsored project 1R01CA78980-01 DISPARITIES IN CANCER SCREENING: THE ROLE OF MEDICAID POLICY:

The proposed project will bring together secondary data from a number of sources to investigate our hypotheses. Nationally representative survey data collected at the state level will be used to study the effects of Medicaid eligibility on breast and cervical cancer screening among low-income populations. Medicaid administrative claims and utilization will allow us to consider the effects of changes in eligibility, as well as physician payment and patient cost sharing on screening among Medicaid enrollees. Cancer registry data will be used to estimate the effects of changes in Medicaid generosity on stage at diagnosis and cancer incidence rates. Finally, we will control for state-level data on healthcare system capacity, infrastructure, and related policy factors.

4.2.1 State infrastructure, policy, and program variables (Aims 1, 2, 3; Panels 1-2, Conceptual Model)

State data on adult Medicaid eligibility for all years of our study will come from Kaiser State Health Facts[37] and the Kaiser Family Foundation (KFF) 50-State Survey, [38] which has been conducted since 2000. We will supplement these sources with information from state Medicaid programs and the Centers for Medicare and Medicaid Services (CMS) as needed. In addition, we will use data from various sources to control for other state-level factors that may impact breast and cervical cancer screening among low-income women. These include data on state healthcare capacity and infrastructure from the Area Resource File (ARF), data on Medicaid managed care enrollment from KFF, [37] and data on state NBCCEDP guidelines that we have collected from various sources, including state program websites. These sources will be compiled into a database with observations at the state-year level, and merged with each of our individual level data sources based on state and year.

4.2.2 Behavioral Risk Factor Surveillance System (BRFSS) (Aim 1; Panels 1-2 Conceptual Model)

Initial analysis will use data from the 2000-2011 BRFSS to assess the effect of Medicaid eligibility on the self reported receipt of breast and cervical cancer screening among low-income women. We will add additional years of data as available to consider future expansions in eligibility. The BRFSS is a cross-sectional telephone survey sponsored by the Centers for Disease Control and Prevention and conducted annually in each state that collects data on coverage, access, health behaviors and preventive care, including specific women's health measures. Response rates ranged from approximately 40% to 70% across states in 2010.[39] Survey weights adjusting for the complex sampling design are also designed to account for population demographics (age group by gender, race/ethnicity, education, marital status, tenure, gender by race/ethnicity, age group by race/ethnicity, phone ownership), adjusting for potential differential non-response across groups. We will use data on length of time since last mammogram or pap test to consider changes in breast and cervical cancer screening after coverage expansions. Self-reported measures of women's cancer screening in the BRFSS have been validated by multiple studies.[40, 41] In addition, demographic data will be used to control for differences in the population across states and years. We will construct measures of income as a percentage of the federal poverty level (FPL) using household income and yearly Census Bureau guidelines for federal poverty standards by household size. Measures including household income and family structure allow us to impute Medicaid eligibility for each observation by state and year.

4.2.3 Medicaid Analytic extract (MAX) (Aims 1 and 2; Panels 1-2 Conceptual Model)

We will purchase data from the Medicaid Analytic extract (MAX) files from CMS to examine changes in screening behavior among adult non-elderly female Medicaid enrollees following changes in physician payment and patient cost sharing. The MAX data are person-level data files on Medicaid eligibility, utilization, and payment for all Medicaid enrollees (regardless of whether or not they used Medicaid services in a given year). Because the MAX data are based on administrative utilization and claims data from states and are not based on self-report, they complement the BRFSS data, which samples the entire population (Medicaid and non-Medicaid) but are subject to

the limitations of self-reported survey data and contain less detailed information on utilization.

MAX data are collected from all states and the District of Columbia and contain Medicaid enrollee-level information on eligibility, demographics, managed care enrollment, fee-for-service (FFS) claims and managed care encounter data. We will use information from ICD-9 diagnosis and procedure codes to examine breast and cervical cancer screening. Current data are available through 2009, and data through at least 2013 will be available during the project period. We will use MAX data from 2003 and 2007-2010 in the first year of the project to assess the effects of pre-reform variation in physician payment and patient cost sharing. These years are chosen both to match years for which complete Medicaid physician fee data are available pre-reform (2003 and 2008) and allow for analysis of patient cost sharing for 4 years before reform. We will add subsequent years of data as they become available and will assess the early effects of any changes in co-payments for breast and cervical cancer screening and physician payment rate increases under the ACA with the 2013 data.

4.2.4 State financial incentive data (Aims 2 and 3; Panel 2, Conceptual Model)

Data on state Medicaid physician fees come from a survey of states conducted by the Urban Institute. We will use data on two sets of measures: a state Medicaid fee index that measures each state's Medicaid fee relative to the national Medicaid average and a Medicaid-to-Medicare fee ratio that provides information on how attractive Medicaid fees in a state are to providers, relative to Medicare payment rates. Data on these fee ratios for all services, primary care services, and obstetric care are available for 2003 and 2008 and will be used to assess the relationship between the generosity of a state's Medicaid physician reimbursement rates and the receipt of screening services by Medicaid enrollees in the state. We will conduct analyses both with and without managed care enrollees included in the sample. To the extent that data on managed care utilization is reliable, the physician fee index may be expected to be related to access since a number of studies have shown that state Medicaid co-

payment levels across states for screening services will come from the Kaiser Family Foundation[37] and state Medicaid programs.

4.2.5 Surveillance, Epidemiology, and End Results (SEER) data (Aim 3; Panel 3, Conceptual Model)

To examine the association of state Medicaid policies with stage at diagnosis and cancer incidence, we will use data from the SEER Program. We will use SEER 18 data on non-elderly adult women with breast cancer and invasive cervical cancer (since SEER does not include in situ cervical cancers) for years 2000-2009 in initial analyses and will update with additional years as they become available. SEER 18 data cover approximately 28% of the US population with data from registries covering 12 states, and include information on patient demographics (age, race, ethnicity, and marital status), cancer site, diagnosis date, stage at diagnosis, and grade or size of tumor.[45] The SEER population is similar to the overall US population in terms of poverty and education, though the data oversample urban minority populations.[46] This makes it well-suited to studying low-income and minority women. The 12 states covered in the SEER data exhibit variation in Medicaid eligibility for adults both across states and over time. As of 2012, 2 of the SEER states offer full Medicaid coverage to childless adults and a number of other SEER states have obtained 1115 waivers allowing for limited coverage expansions to higher income limits for parents and/or childless adults.[37] We will use information on county attributes in SEER to consider effects among women in counties with a low median income or high poverty rate in order to consider the overall effects of Medicaid expansions among target populations. We will consider individual-level stage at diagnosis for breast cancer and county-level incidence rates for breast cancer and invasive cervical cancer.

4.3 Variables

We will draw on the data sources above, combining the 3 individual-level datasets with state-level variables. Key variables will be defined as outlined in Table 2.

Table 2. Key variable definitions and source

Variable	Definition	Source	Aims
Outcomes			
Mammography	Receipt of annual or biennial mammogram for women in recommended age ranges	BRFSS; MAX	1 & 2
Pap test	Receipt of pap test in the past 1 or 3 years for women in recommended age ranges	BRFSS; MAX	1 & 2
Stage at diagnosis	SEER summary stage for breast cancer cases (in situ, localized, regional. or distant)	SEER	3
Incidence	Cases of breast cancer and invasive cervical cancer per population	SEER	3
Policy variables			
Medicaid eligibility	Individual eligibility based on household income and family size	KFF, BRFSS	1 & 3
Physician payment	State-level Medicaid fee index and Medicaid-to-Medicare fee ratio	Urban Institute	2
Cost sharing	Medicaid co-payment amount for mammogram or pap test	KFF, Medicaid sites	2
Individual-level controls			
Age	Continuous variable ranging from 18-64		
Race	Categorical variable with values for White, Black, Other race	BRFSS, MAX	1-3
Ethnicity	Dichotomous variable indicating Hispanic origin	SEER	
Education	Highest education level in 6 categories (from kindergarten or less to college grad)	BRFSS	1
Marital status	Dichotomous variable measuring married vs. not married	BRFSS	1
Income	Household income in 8 categories ranging from < $10,000 to $75,000+	BRFSS	1
Employment	Dichotomous variable measuring employed vs. unemployed or not in workforce	BRFSS	1
State-level controls			
Physician supply	Number of physicians, primary care physicians, and specialists per population	ARF	1-3
Hospital capacity	Number of general non-federal short-stay hospital beds per capita	ARF	1-3
Medicaid managed care	Percentage of state Medicaid enrollees in any managed care or in comprehensive	KFF	1-3
NBCCEDP Generosity	Eligibility level, and program option (indicating scope of provider participation) for state NBCCEDP	State program websites	1-3

4.4 Research Design and Methods

Our analytic approach will employ a quasi-experimental design to examine how changes in Medicaid eligibility, physician payment, and patient cost sharing affect the receipt of mammograms and pap tests, including guideline-consistent screening, among low-income women ages 19-64, as well as how changes in each of these Medicaid policy variables affects cancer outcomes, including stage at diagnosis and cancer incidence. We will take advantage of variation in Medicaid policy both across states and within states over time to identify the effects of policy changes on our outcomes of interest. Specifically, we will use difference-in-difference-in-differences (DDD), and state and year fixed effects models to compare changes in outcomes among groups that would have been affected by changes in Medicaid policy (eligibility, payment rates, or cost sharing) to similar groups that were not subject to policy changes.

4.4. 1 Aim 1: Medicaid eligibility and breast and cervical cancer screening

Our analysis for Aim 1 will use the sample of non-elderly adult women in the BRFSS to compare screening for low-income women who become eligible due to expansions to similar low-income women in states without expansions and women within the same state whose eligibility does not change, controlling for individual demographics. Each expansion state will be matched to one or more control states[20] (based on geographic region and other baseline state characteristics). We will estimate DDD regressions of the form

$$Y_{ijt} = \beta_0 + \beta_1 X_{ijt} + \beta_2\, \text{EXP\_ELIGIBLE}_{ij} + \beta 3 \text{EXP\_STATE}_j + \beta_5(\text{EXP\_ELIGIBLE}_{ii} \times \text{EXP\_STATE}_j)$$
$$+ \beta_6(\text{EXP\_ELIGIBLE}_{ii} \times \text{POST}_{jt}) + \beta_7 (\text{EXP\_STATE}_j \times \text{POST}_{jt})$$
$$+ \beta_8(\text{EXP\_ELIGIBLE}^{ii} \times \text{EXP\_STATE}_j \times \text{POST}_{jt}) + y_j + T_t + \mu_{jt} + \varepsilon_{ijt}$$

for each of our screening outcomes (mammogram or pap test within given timeframe) Y_{ijt}, where i indexes individuals, j indexes states, and t indexes years. EXP_ELIGIBLE$_{ij}$ is an indicator equal to one for individuals whose eligibility status

would change from ineligible to eligible due to a Medicaid expansion in their state or the matched treatment state (for those in a control state). EXP_STATE_j an indicator equal to one in expansion states. $POST_{jt}$ is an indicator equal to one in the expansion state and matched control states after implementation of a state expansion. This variable will be specific to sets of matched states since timing of expansions can vary. The X_{ijt} term is a vector of demographic covariates, including age, marital status, education, employment, household income, and race/ethnicity. The term y_j represents state fixed effects that control for time-invariant state characteristics, T_i represents year fixed effects to control for secular trends in screening, μ_{jt} is a random effect for each matched set of treatment and control states, and ε_{ijt} is an individualspecific error term. The coefficient of interest is β_8 the DDD estimate, which represents the effect of an expansion on screening for the newly eligible relative to controls in the same state and in non-expansion states. In addition, we will consider simple difference-in-difference (DD) models comparing screening in expansion and control states to estimate an overall change in screening in these states, though the DDD model is our preferred specification since it isolates the effect on those newly eligible. We will estimate linear probability models for ease of interpretation and to avoid issues with interaction terms in non-linear models, [47] and test the sensitivity of our results to the use of non-linear models. Analyses will employ survey weights to account for the complex sampling strategy. Standard errors will be clustered at the state level and we will consider alternate strategies for computing standard errors in the DDD framework.[48]

In addition to considering the effect of eligibility on screening among all low-income women, we will estimate models to test whether effects of expansions on screening are larger among racial and ethnic minorities (e.g. whether eligibility expansions reduce racial disparities in screening). To test the disparities hypothesis, we will estimate models similar to (1) above but stratified by racial and ethnic group. This will allow us to consider the effect of changes in eligibility on screening among minority women relative to non-minority women who become eligible due to Medicaid expansions. We will separately consider disparities between non-Hispanic whites and both African Americans and Hispanics. We will also consider a minority classification including Asians, though they are a smaller percentage of our samples

and we may not have adequate power for a separate analysis of Asians. Finally, we will also consider how screening rates changed among Medicaid enrollees using the MAX data, which include a larger sample of all Medicaid enrollees and are based on administrative data rather than self-report. We will compare screening rates across states with and without expansions in a simple DD framework since the MAX data include only Medicaid enrollees and no relevant control group.

From NHLBI sponsored project 1R01HL114432-01A1 DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES?

Approach: Overview of Study Design

Our proposed national longitudinal study will assess changes in park policies and programs in 25 representative cities and 200 parks over a 3 year period. We will conceptualize effort to alleviate or foster health disparities based upon a finding of differential allocation of resources across high and low income neighborhoods. In addition we will examine whether there is an association between changes in resource allocation, park management and changes in park-based population physical activity. In each of the cities, we will randomly select eight parks that meet criteria to be considered "neighborhood parks" and collect data on park characteristics, budgets, staffing and programming, park characteristics, characteristics of the local neighborhood, a**nd conduct key, stakeholder interviews.** In collaboration with the City Parks Alliance and the Trust for Public Land's Center for City Park Excellence, we will recruit and train citizen-scientists from each of the 25 cities to conduct systematic observations of physical activity and park use according to the SOPARC protocol. We will collect data **in the first and third years** in order to identify how changes in resources are allocated across high and low-income neighborhoods.

Preliminary Studies: The proposed project will be led by Principal Investigator Deborah Cohen, MD, MPH (RAND) and Co-Investigator Thomas McKenzie, PhD. The investigators have a wealth of experience in the relevant areas of research and

methodological approaches needed to carry out the proposed research and they have worked together successfully in the past. Along with co-investigator Catherine Nagel of the City Parks Alliance, the study team combines multidisciplinary strengths from medicine, exercise and sport sciences, and parks and recreation policy and management.

Creation and Validation of SOPARC: We developed the SOPARC tool specifically to study the interaction of people and parks by obtaining observational data on the number, age, and race/ethnicity of park users and their physical activity (PA) levels during play and leisure opportunities. The system is based on momentary time sampling and uses Planned Activity Check recording, which involves group time sampling techniques [35]. SOPARC was adapted from the System for Observing Play and Leisure Activity in Youth (SOPLAY) [36]. Systematic scans of target areas are made during designated measurement periods. During a scan, the PA of each individual in a target area is coded as sedentary (e.g., lying down, sitting, or standing), walking, or vigorous (e.g. biking, in-line skating, jogging). Because these activity codes have been validated by heart rate monitoring, they permit energy expenditure rates.(EER) to be estimated [37, 38]. Separate scans are made for males and females. The context of the physical space, such as whether supervision, organized activities, and equipment are present is documented. The full protocol appears in the Appendix.

Reliability. Reliabilities of SOPARC observations for area contexts (i.e., usable, accessible, supervised, organized, equipped) exceeded 94%. Rates of agreement for individual characteristics were greater than 0.88 [39]. *Validity.* We conducted a rigorous assessment of the minimum number of observations that are needed to estimate weekly use of parks. Among 2 parks in each of 5 cities observed in 2 seasons, 13-14 hours a day, 7 days of the week in clement weather, we counted 76,632 individuals, an average of 547 persons per day (range 155-786). There was an average of 95% agreement between observers (standard deviation=3.2%). Three randomly chosen days of data collection 4 times a day were sufficient to estimate the number of users (average alpha=0.88 and ICC=0.76), but a 4 days per week, 4 times per day schedule was needed to robustly measure walking and sedentary behavior [40]. The latter is the schedule we propose for this study.

Concerns re: Observation of Race/Ethnicity: Because race/ethnicity is not easily observed, the agreement between observers for this parameter is lower than for other characteristics (0.82) [41], but still acceptable. It is important to recognize that the data collected about race/ethnicity are estimated: we do not ask every park user about his or her race/ethnicity, and it would not be feasible to do so. A justification for assessing race/ethnicity by observation is that people generally make judgments about backgrounds of others, based on appearance, even if those superficial judgments are inaccurate. Our findings will be compared to available census data describing the self-reported race/ethnicity of local residents. Without some estimate of parks users' race/ethnicity, we cannot asses racial/ethnic disparities in use and physical activity. In reporting study findings, we will clearly indicate that the race/ethnicity data are based on observation, not self-report. We will also conduct a sensitivity analysis to explore the potential bias of our observations.

Contribution of Parks to Physical Activity: By triangulating observed park use and physical activity in parks and modeling physical activity based upon the NHANES data that used accelerometers to measure physical activity, we estimated that parks contribute to about 10% of all physical activity, but this includes more than 30% of vigorous physical activity. In contrast to moderate physical activity, vigorous PA is necessary for cardiovascular fitness and for healthy bone growth and muscle development. However the relative contribution of parks to vigorous PA varies considerably. In one preliminary study we found that a park in a low SES community accounted for 26.6% of vigorous PA, while in a higher SES community it accounted for 35.6% among residents in a ½ mile radius. This study identifies performance measures and benchmarks for park-based physical activity. (Paper under review). If localities can identify such differences, they can take steps to mitigate them, if the differences are due to modifiable characteristics, like programming and staffing.

Sampling Strategy: We will use a two-stage sampling design. First, we will select the 25 cities for the study by strata and then sample 8 urban parks based upon neighborhood SES within every selected city. The eligible cities for the

study will all be populous incorporated places in the Continental US with a population of 100,000 or more as defined by the Census Bureau. We will stratify these cities by region (West, South, Mid West and North-East) and by size (three strata: cities with population above one million, cities with a population above 200,000, but less than one million, and cities with a population below 200,000). There are only 9 cities with a population above 1,000,000. We will merge the.9 large cities into a single stratum. We will use an adaptive algorithm that allocates cities to strata in such a way that effective sample sizes across strata are fairly homogeneous [44]. This sampling design will generate a nationally representative sample of the US cities with a population of 100,000 or more. Because policies cluster by jurisdiction, we are sampling at the city level, rather than the park level. For every sampled city we will compile a comprehensive list of parks that satisfy our definition of "urban park." In general, these are parks that range in size between 3 to 15 acres. We will define the park neighborhood as the area comprised in a half-mile radius from the park. We will stratify parks based on the empirical distribution of the neighborhood poverty levels within each city. We will use either the median or quartiles depending on how many urban parks are in each city. We will randomly select equal numbers of parks from each poverty stratum within a city. We will also ensure that the 8 parks chosen within a city are geographically dispersed to avoid strong spatial correlations in the observations.

Data Collection

Data in the proposed study will come from our own primary data collection and from secondary sources. Each of the tools and protocols to be used is described below. A table summarizing predictors, control variables, and outcome variables and the data collection tools used to measure them is contained in the appendix.

Primary/Secondary Data Collection Tools and Methods: Our primary data collection will include direct observation of park activity using SOPARC, direct observation of the presence or absence of various features of the park and surrounding neighborhood, interviews with park staff in which information about available

programming and outreach efforts and staffing patterns, **key stakeholder interviews,** collection of local crime and weather data.

Systematic Observations of Play and Recreation i n Communities (SOPARC). SOPARC is designed for collecting objective data on the number of people in a park, their gender, race/ethnicity, age, and the physical activity in which they are engaging while in the park. Prior to collecting data with the SOPARC tool, field staff will map each park so that all the areas within its boundaries are divided into discrete, non-overlapping activity areas in which it is possible to observe all of the people in the area. Mapping can be accomplished as follows. First we download a satellite image of the park using Google Maps. Second, we make a site visit to the park to complete or correct the park features that are missing or different from the satellite image, such as anything under trees or overhangs, or even rooms within buildings. We label the various activity areas and demarcate boundaries to distinguish the different target areas for observation. Target areas are usually distinguished by function, so that the playground, basketball courts, picnic areas, etc. will be observed separately. The map is then re-created using PowerPoint so that the target areas are numbered and specified. A second visit to the park is needed to verify the accuracy of the target areas and to order the sequence in which the park areas will be observed .An independent observer checks the proposed park subdivisions, boundaries, and order of visitation. Differences of opinion will be reconciled by consensus between the two field staff. If no agreement is reached, a decision will be made in consultation with RAND staff. (See SOPARC protocol and sample map in the Appendix).

SOPARC yields both process and outcome variables. Process variables are those that reflect contextual characteristics of the physical and social environment. Process variables will include (1) accessibility, (2) usability, and (3) whether or not the area is provided with supervision, organized activities, and equipment. Process variables are recorded as one scan of one activity area. To generate a composite score for each process variable (e.g., overall accessibility of activity areas within a given park on a given day), we will aggregate scores on a process variable across all activity areas within a park and then across all four periods of observation within the same day.

Thus, for each park, there will be four composite scores for each process variable – one for each day of observation.

Data collection for outcome variables using SOPARC is conducted by observers rotating through the park systematically and counting the number of park users by gender, ethnicity, and age groupings and their activity levels in all physical activity settings (target areas) within a park, as well as the absolute and total proportion of users by age group, gender, and race/ethnicity. Physical activity levels include (1) sedentary, walking, and vigorous physical activity and (2) estimated energy expenditure per observation period calculated by assigning estimated METs to the three physical activity levels [10]. The amount of energy expended while walking briskly for 1 hour is about 4.5 METS. METS can be aggregated across specific physical activity areas (e.g. playground or basketball courts) or across the entire park. Because our interest is in moderate-to-vigorous physical activity (MVPA), we will combine walking and vigorous physical activity to obtain an estimate of MVPA.

SOPARC observations will be made in each designated activity area (approximately 20 target areas per park) within each park on four randomly selected days during the spring. In the event of inclement weather (e.g., rain), we will postpone observations until the following week. During an observation day, four rotations of all areas in the park will be made during four one-hour periods. We will choose a random schedule so that every hour of the day can be observed at least once. Thus, we will not systematically miss people if they come for classes that are scheduled between the observation times. For example, on Monday, we may observe the park at 8 a.m., 10 a.m., 2 p.m., and 6 p.m., and on Tuesday, we may observe the park at 9 a.m., 12 p.m., 4 p.m., and 5 p.m. The same time-of-day schedule will be used at every park.

Park Facilities and Amenities Checklist. This checklist was first developed as a part of the Trial of Activity for Adolescent Girls (TAAG) study funded by NHLBI. It was used in 6 cities to assess over 400 parks. In each city two observers used the checklist to independently assess 10% of parks from the larger sample, and its reliability was excellent. The checklist covers the presence or absence of a variety of park features and amenities and enumerates features and amenities where there

is more than one, such as the number of basketball hoops or baseball diamonds.(see Appendix for the full list of features and amenities assessed). Data collectors for the proposed study will code park features and amenities on the checklist while mapping the park to prepare for observation of park use with SOPARC.

Neighborhood Settings Checklist. In addition to assessing characteristics of the parks, data collectors will walk through the area surrounding the park and document the mix of land use (i.e., the percentage of land use that is commercial, residential, and industrial), as well as the type of streets, number of lanes of traffic, and access to sidewalks in the areas surrounding the park. (See Appendix). We will adapt this form to collect information on the number and type of neighborhood commercial establishments selling food, including fast food and convenience stores, and whether food trucks or food carts are in or around the park during each observation..

BRAT-DO (Bedimo-Runq Assessment Tool-Direct Observation). This comprehensive assessment of 181 park features will be adapted for use for our study. It has many reliable items such as weather (cloudy vs. sunny), signs (e.g., no dogs allowed), litter, and drinking fountains that can enrich the data collection tools we have used in the past [45]. Domain reliability for BRAT-DO was 87%, and overall geographic area reliability was 88%. Overall domain validity was 79% and overall geographic area validity was 82% [46].

Park Staff Questionnaire. This questionnaire was developed as part of our SOPARC validation study to assess how parks provide services to their community. (See Appendix.) Data collectors will use the form to conduct interviews with park staff to obtain information about park policies, programming and outreach efforts, and park staffing patterns (i.e., number of full-time and part-time employees and volunteers).

Crime Data. Because crime rates are considered a barrier to physical activity, we will collect local crime data for each year of the study as an independent variable to use in the analysis. We will operationalize this as violent crime per 100,000 residents (aggravated assault, murder, robbery and rape). The relevant geographic area

chosen will be the one most closely associated with the half-mile radius around each neighborhood park.

Key Stakeholder Interviews: To enhance understanding of local non-park-based influences on physical activity within each jurisdiction, we will conduct semi-structured telephone interviews with key local stakeholders who have extensive knowledge of the local jurisdiction. This qualitative component of the project will supplement the quantitative assessment by allowing for exploration of influences on park use at the local level that may not already be covered in the quantitative component of the project. In each city we will interview at least five stakeholders with the following community roles: 1) a local elected official (e.g., councilmember, mayor) who represents an area which includes at least one of our study parks, 2) civic organization official (e.g., Rotary Club, Kiwanis Club), 3) sports organization official (e.g., Little League or American Youth Soccer Organization), 4) Park Advocacy organization (e.g., friends of the park, nature conservancy), and 5) minority organization (e.g., NAACP, NCNW, or National Council of La Raza). Each stakeholder will be interviewed twice, once in the year after each wave of quantitative data have been collected and analyzed. Topics covered in the interview will include how the stakeholder's organization might interface with public parks, the role of public parks for their constituency, unique local factors that might influence use of local parks such as demands by local residents or: community groups, unique crime/gang profiles, and budgetary and leadership issues. We will also use the qualitative interviews to drill down and interpret quantitative findings on park use within each jurisdiction, including observed disparities in park use. Specifically, we will present stakeholders with basic quantitative findings about park usage obtained at each wave and ask open-ended list and relational questions [47] to understand the range and types of local non-park influences on park use within the jurisdiction. For example, if one park within the jurisdiction is particularly underutilized relative to other parks within the same jurisdiction, we would ask stakeholders to describe the most important factors that might be contributing to this disparity in utilization and what changes could be made, if any to reduce this disparity. At the second wave of key stakeholder interviews, we will

also assess changes in the community since the first interview that may have impacted park utilization. Each interview will be conducted by a researcher (C. Vaughan) with experience conducting qualitative interviews. A note-taker will record interviewee's comments. To analyze the qualitative data, two coders will independently generate a list of themes based on a prior understanding of the topic under investigation and a thorough review of text from each set of interview notes. To winnow down the initial set of themes to arrive at the final set of the most relevant themes, the investigative team will discuss the initial set of themes and seek to arrive at consensus regarding the most relevant set of themes. This analysis will allow u to provide rich feedback to individual jurisdictions regarding community-level influences that may be impacting park-based physical activity within their jurisdiction and can potentially be modified to increase park-based physical activity, as well as to compare and contrast the types of local non-park influences on physical activity across the jurisdictions studied.

Other Data Sources and Variables: Secondary data sources include data from the US Census and the National. Climatic Data Center. We will also request marketing plans for each city and the city's park master plan.

US Census. We will use information from the most recent US Census to assess the neighborhoods surrounding the parks in terms of their socioeconomic status (as indexed by median income of residents); population density; and residential composition by gender, race/ethnicity, and age. These variables will be included as covariates in all adjusted analyses, because they are potential confounding factors in the relationships between park characteristics and park use and MVPA.

National Climatic Data Center. For every day that park observations are conducted, we will collect data on maximum and minimum temperatures from the nearest weather station. Temperature will be recorded for each park. Temperature data will be obtained from the National Climatic Data Center. (http://www.ncdc.noaa.gov/oa/ncdc. html).

Data Analysis. The sampling design will yield a multilevel data structure in. which the repeated measures over time are taken for each park, and parks are nested within cities. We will apply a set of hierarchical models for analysis, controlling for environmental and economic covariates, such as crime rate and unemployment rate. We will also account for heterogeneity among cities. **Health disparities will be measured by differences in park use and park-based physical activity by neighborhood SES.** We will aggregate the data to the level of park by year. In what follows, we assume that all these outcomes can be modeled with a normal distribution. If the data suggest that normality is not tenable, we will investigate other distributions, e.g., the Poisson model for the number of park users. We will conduct both unweighted and weighted analysis using sampling weights. If the design effect is not ignorable, we will adopt the weighted analysis.

Analysis Plan

Aim 1. To determine whether there are systematic differences in park resources and park use, programming and management practices depending upon the socioeconomic status of the park neighborhoods in a representative sample of American cities.

The analysis under this aim is based on the cross-sectional data of the baseline (the first wave). We will apply a hierarchical model to the park-level observation. Let $Y_{ij(i)}$ denote the outcome (resources, programming, practices, or park use) at park j nested in city i, i=1...25, j(i)=1 ...8. The basic model is

$$Y_{ij(i)} = \alpha_i + \lambda \times SES_{j(i)} + \beta X_{i,j(i)} + e_{i,j(i)}, \quad (1)$$

where a_i accounts for the between-city difference, $SES_{j(i)}$ is a park's socioeconomic status, $\beta X_{i,j(i)}$ are the effects of the controlled covariates. The last term $e_{i,j(i)}$ is the random error. We will try both a categorical SES (e.g., high/low) and a continuous SES (% poverty). The main interest is to infer the parameter A for the effect of SES.

We will first implement the random-effect approach for the city effect a_i. Our sampling design (parks with differential SES in each city) also allows for the fixed-effect approach to a_i. We will conduct a sensitivity check by applying the fixed-effect approach. Both approaches can be readily implemented in most general-purpose statistical software packages such as SAS and R. If the results show notable differences between the two technical approaches, we will further implement a model averaging estimator [49] to combine the two results. Otherwise we will adopt the random-effect approach for its superior efficiency and richer inference tools such as the empirical best linear unbiased prediction (EBLUP).

Our previous study suggests that some outcomes (e.g., number of park users) have a nonlinear relationship with the covariates. It is also possible that some resource outcomes (e.g., number of part-time staff, number of activities) can be better modeled by the Poisson or zero-inflated Poisson distributions. We note that the conceptual model (1) can be readily adapted to these cases, for example, using an adequate transformation on the outcome for nonlinearity, and using a generalized linear (mixed) model for the exponential family distributions with the same mean function as (1).

The Writing Process for your Approaches Section

Since the Approach and Significance sections are arguably the most important parts of your proposal, you will want to take extra time to get the advice you need to ensure that they will get your message across. This usually involves a multi-step proposal writing process. If you are a single author, you will want to get someone else in your field that you trust to read each portion of the proposal and comment on it. You will also want to send it to an outside reviewer who is a practitioner or who may have knowledge of the research topic but is not another scientific expert in your methods and field. These outside reviewers are important to check that you have included everything you should on the science and that your argument is understandable to a practitioner, advocate, or someone else who may not be familiar with your scientific topic. Outside reviewers will need sufficient time – anywhere from several weeks to a month, to read through your draft carefully. Depending on

your relationship to these reviewers, you may want to send them multiple drafts until the proposal is ready to go out. However, it is not recommended to send outside reviewers more than one or two versions of the proposal.

If you are writing an interdisciplinary proposal, have multiple co-PIs, or are using multi-methods strategies, you will want to develop a writing plan that draws on the expertise of all contributors to the study. If you are using multiple methods, it is advisable to have the methods expert for each method contribute sections on their methods and literature related to the topic from their discipline or approach. In some cases, one person takes the lead in writing the proposal while other teams split the work up equally. In either case, you will need to give the entire team of co-PIs time to review the proposal and comment on it. If several people are doing the initial writing, one team member should go over the entire proposal and standardize it for consistency and style. As with other proposals, these proposals should also go to outside reviewers.

Preliminary Data for New Applicants

Direct from NIH:

Preliminary Studies for New Applications: For new applications, include information on Preliminary Studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. Except for Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data.

What this means:

NIH introduced this section in January 2010 as part of its application overhaul, and you should include this only if your application is new. And keep in mind that this section is included as part of your 12-page Research Strategy.

Although reviewers will not place as much emphasis on Preliminary Data for early-stage investigators as they do for more established researchers, every new R01 application should include details regarding the project director(s)/principal investigator(s)'s preliminary studies, data and/or experience related to the proposal.

In addition, NIAID indicates that this preliminary data shows that you are on the right track with your research, and your Specific Aims should build on this previous research as a foundation. "Reviewers use this section together with the biographical sketches to assess the investigator peer review criterion, reflecting your competence to do this work," the institute states. Therefore, preliminary data builds reviewer confidence that you can handle the technologies involved, understand the methods and effectively interpret the research's results.

NIAID suggests that you include the following details in your Preliminary Studies section:

- Critically interpret preliminary results.
  - o Provide alternative meanings to the data to show you have thoroughly considered the problem and can meet future challenges.
  - o If you are not critical of your own results, you can be sure reviewers will be.
- Include sufficient information to show you know what you are talking about.
  - o The more complex your proposal, the more data you will need.
  - o Explain how your early work has prepared you for this new project.
- Focus on *your* preliminary or unpublished data from your research, although you may include other people's publications. If you present results from other labs, be sure to clearly indicate which data are yours and which are not.
- Include previous experience that shows you can direct the proposed research and achieve its aims.

What to Include and What to Leave Out

The first purpose when presenting preliminary data is to demonstrate feasibility and that you have the necessary expertise to carry out the procedures you propose in the Research Methods. Consequently, some applicants wonder if they should include contradictory data in their applications.

In response, reviewers point out that this section's purpose focuses more on your ability to successfully collect and analyze the data rather than on the results of that data.

Preliminary data supporting your hypothesis and research plan, however, are potent evidence in your favor. They indicate that you are on the right track, and reviewers weigh this heavily. At the same time, there are subtleties to reporting this data, and possible variations involve the following:

1. Primacy of the outcomes,
2. Positive/negative results, and
3. Statistical power of your preliminary studies to detect effects (for quantitative techniques).

And there are several possible outcomes and resulting implications for your proposal based upon your preliminary data:

Positive/Null/ Negative	Statistical Power	Implications
Positive	Adequate	Reviewer may wonder why you need to conduct the proposed study because you already have strong support for your hypothesis.
Null/Negative	Adequate	This result presents the biggest potential challenge for your proposal because your preliminary data shows you failed to detect effects, although you had adequate power to do so.
Positive	Inadequate	This is your most desirable potential outcome. Because the statistical power was insufficient to detect effects, your statistical test for this outcome presumably was not significant (if it is, you have to suspect chance). Therefore, you are on the right track with your preliminary studies, and your results bear the replication you are proposing.
Null/Negative	Inadequate	Although this situation presents a challenge, you can address it by implying there was inadequate statistical power to differentiate between the means as not to be believed or is a product of chance.

Courtesy: William Gerin, PhD

Your main challenge with preliminary data is the null result as your primary outcome. This is not necessarily fatal if your sample size was small and your statistical power was inadequate. In this case, you would not necessarily have to mention the data's statistical power, and the reviewer will examine the sample size and understand the limitations there.

When you do present contradictory data, be sure to then explain what you have done to generate confirmatory data that supports your hypothesis.

Review This Example

Here is a partial example of a Pilot Studies section from a successful NIH application.

From NIAAA sponsored project 1R01AA021136-01A1 A RANDOMIZED CLINICAL TRIAL OF CULTURALLY TAILORED MI

C.1 CTMI pilot study feasibility, relevance, and acceptability: Pilot studies should demonstrate the intervention's feasibility, acceptability, and relevance to the target population [127]. Despite having a part-time staff due to a limited K budget, the pilot had strong recruitment figures. Within the projected study time frame, anticipated enrollment quota were exceeded by 45% over projected figures, (n=58, originally proposed n=40). Over half of participants (53%) were male and retention rates were 84% at 2 and 6-months. Relevance and acceptability was demonstrated by community support, i.e. invitations to recruit at churches and free radio advertising because the study was seen to be beneficial to the community, and insider tips on where to recruit. Second, when participants were asked about the study during its formative stages [71], nearly all participants (95%) believed that discussing culture was relevant to their drinking and reported high treatment satisfaction and engagement ratings (both $M = 3.58$, 0=not at all, 4 = highly engaged/satisfied).

C.2 Pilot Study Methods: Pilot study participants were Latinos (n=58) who met criteria for hazardous drinking (> 5/4 drinks/occasion for men/women, or > 14/7 drinks for men/women). High weekly levels were reported among men ($m = 44$ drinks/week, SD = 42.57), and women ($M = 18$ drinks/week, $SD = 15.56$). Mean age was 35 years, 56% were male, 54% were U.S. born, and 48% reported annual income of $20,000 or less. Participants were moderately to highly acculturated, as measured by the Short Acculturation Scale for Hispanics [128] ($x = 3.12$, SD=.78). Baseline analyses found no significant differences between treatment conditions at baseline, making it unlikely that the treatment effects in the pilot study could be attributed to regression to the mean. Participants were randomly assigned to complete

a baseline assessment, and then to receive CTMI or Ml intervention, delivered by a trained interventionist. The Pl conducted the Ml and CTMI training for the six interventionists, who were all graduate or post-graduate level clinical psychologists. All were non-Latinos (Whites n=4, Asian, n=2), most (n=4) were women, and all were English-speaking. Following the CTMI or Ml intervention, participants completed an intervention evaluation form and completed follow-up assessments at 2 and 6 months. Graduated-Frequency assessed frequency of (heavy) drinking days/month, and the DrlnC and its subscales measured alcohol-related consequences. For example, the DrlnC Impulse, an important subscale, assesses interpersonal violence, getting arrested for driving under the influence, and increased propensity for drug use. Repeated measures were conducted with all dependent measures using GLM to assess time by treatment effects.

C.3 Pilot study results: **In the pilot study, we compared two active treatments and did not compare Ml to standard care. Our comparison of tailored to un-tailored treatment is the most rigorous test, rarely accomplished but necessary to advance the science of cultural adaptation.** Thus, since the study compared two active treatments, reductions after both were also expected. Second, it was hypothesized that declines in drinking and related negative consequences would be greater for CTMI vs. Ml.

The first hypothesis was supported. Results comparing the two active treatments revealed significant declines for both on drinking days/month (F 1, 45) = 34.23, p < .000), heavy drinking days/month (F (1, 45) = 20.70, p < .001), DrlnC (total, F(1,44) = 34.93, p < .001; and DrlnC subscales: Impulse F (1,44) = 39.26,p < .001; Interpersonal F (1, 44) = 23.39, p < .001; lntrapersonal F (1, 44) = 17.43, p < .001; Physical F (1, 44) = 29.31,p <.001; Control F (1, 44) = 35.61, p < .001; Social F (1, 44) = 11.87, p < .001).

The second hypothesis was also supported. A significant time by treatment interaction on DrlnC Impulse and a trend for heavy drinking days/month, with at least medium effect sizes on both, suggested that CTMI, compared to Ml resulted in significantly greater reductions in the number of impulsive behaviors related to

drinking and a trend for heavy drinking days. These reductions were greater in the CTMI than in the Ml at 2- months, with continuing reductions in CTMI at six months compared to Ml. Greater reductions in DrlnC for CTMI over time were observed in the DrlnC subscale Impulse (F $(1, 44) = 7.48$, p = .009, eta^2 = .14, f = .40, large effect) than for the Ml condition. Second, a trend for number of heavy drinking days/month, also an important outcome as heavy drinking days are noted to increase risk for negative consequences (F $(1, 44)$ = 3.18, p = .08, eta2 = .10, f = .33, medium effect) was found. Cohen's recommended conversion of eta2 to the f statistic is recommended for ANOVAs [129]. **These promising statistical effect sizes in favor of the CTMI are noteworthy given the pilot study's low power, and support the need to replicate the pilot study with a larger sample as proposed in the current study.**

C.4 Measure of Drinking in response to Acculturation Stressors (DAS) [109] was developed and validated in the context of the pilot CTMI. Repeated-measures ANOVA examined differences on the number of DrlnC consequences by treatment condition, stress level, and their interaction, from baseline to two and six-month follow-up. Between subjects analysis revealed significant main effects for treatment (F $(1, 37)$ 4.42, p = .042) and stress level (F $(1, 37)$ = 17.21, p < .001). Within-subjects analysis revealed a significant stress by time interaction (F $(2, 74)$ = 4.18, p = .019). High stress participants reported a greater decrease in problems over time than low stress, indicating that alcohol interventions should focus on acculturation stress.

C.5 Extending the CTMI to Spanish-speakers. Many pilot CTMI potential volunteers were unable to speak English but met study eligibility criteria. Therefore, the Pl piloted Ml and CTMI with Spanish speaking individuals (n=3) using a trained Ml Spanish bilingual interventionist in the pilot CTMI. Participants who received the pilot CTMI in Spanish were retained in treatment at 2 and 6-months, and were highly satisfied (4.0 out of a scale of 4.0) and engaged (4.0 out of 4.0). Based on these positive findings, the CTMI will be extended to Spanish-speaking individuals in the current proposal using Spanish-speaking motivational interventionists in both the standard and tailored versions.

C.6 CTMI Pilot Study: How Lessons learned will inform the proposed study.
A major lesson learned was how to successfully negotiate between different worlds (academic/community, Latino/non-Latino, Spanish/non Spanish speaking) to accomplish the research. The importance of navigating these worlds as a researcher doing work with Latino communities cannot be over-emphasized. Without it, successful study completion is compromised (130). The Pl has unique experience and skills set on community-based recruitment, building community researcher collaboration, and with training and supervising a bi-lingual staff. It was also learned that community members had varying degrees of research training and different assumptions about research conduct. Therefore, the Pl learned how to screen, select, and train study staff in a way that integrated community perspectives while retaining a high standard of study conduct. Third, community endorsement, key to study success, was defined as the perception that the CTMI was a <u>community service</u>. In response, the Pl formed a SECHC Community Advisory Board for the proposed study. Patient preferences in intervention participation (i.e. weekends, often with friends/family) were also observed. As a result, research staff and more than one interventionist will be on call during these times in the proposed study. The Pl also learned important lessons on training CTMI interventionists.

Progress Report for Renewal/Revision Applications

Direct from NIH:

Progress Report for Renewal and Revision Applications. For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant budget reductions. A list of publications, patents, and other printed materials should be included in the Progress Report Publication List attachment; do not include that information here.

If you are submitting a renewal or revision application, you will provide a progress report rather than preliminary studies information. This progress report should contain the following information, according to NIAID:

- Your project period beginning and end dates.
- A summary of your findings' importance as related to your Specific Aims.
- Published and unpublished results, highlighting your progress toward achieving your Specific Aims.

When writing these reports, reviewers recommend that you indicate the dates and restate the Specific Aims. Then you should include a narrative summary of the progress you have made for each aim. At the same time, you will not have to relist your publications because you will upload them as a separate document. Ideally, your progress report should be roughly a page or two.

OVERALL IMPACT BRINGS EVERYTHING TOGETHER

Direct from NIH (SF424 (R&R) Application Guide, Version C, for NIH and Other PHS Agencies):

Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

Overall Impact (From NOT-OD-09-025)

- Overall Impact is not a sixth review criterion.
- Reviewers will write a paragraph summarizing the factors that informed their Overall Impact score.
- Overall Impact is not necessarily the arithmetic mean of the scores for the scored review criteria.
- Overall Impact takes into consideration, but is distinct from, the scored review criteria.
- Overall Impact is the synthesis/integration of the five core review criteria that are scored individually and the additional review criteria which are not scored individually.
- To evaluate, the reviewer(s) make an assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the scored review criteria, and additional review criteria (as applicable for the project proposed).
  o Likelihood (i.e., probability) is primarily derived from the investigator(s), approach and environment criteria.
  o Sustained powerful influence is primarily derived from the significance and innovation criteria.
  o Research field(s) may vary widely, so it would be helpful if reviewers identify in their reviews the research field(s) they believe will be influenced by each project.

What this means:

Many applicants ask, "What is 'impact,' and how can I show it in my proposal?" And as stated earlier, investigators frequently are confused by the difference between "significance" and "impact."

Essentially, NIH has instructed reviewers to evaluate significance by asking, "If your research is conducted effectively, then how important will your results be?" The big picture in reviewers' minds is whether the research is worth doing.

Impact, on the other hand, includes the likelihood that the research will succeed. If you can not carry out the project effectively, then there will not be any impact, even if the research is highly significant.

NIH has instructed reviewers to weigh all of the individual core criteria – innovation, significance, approach, environment and investigators — when examining your application and arrive at an overall impact score. Unfortunately, there is no magic formula reviewers use to equate your individual criterion scores to your overall impact score. Each will likely rate each criterion differently. Some will base your impact score almost entirely on your experimental approach, as they did under the former application review process. Others will be much more concerned with Innovation and Significance.

The specific grant you are seeking will also affect your Overall Impact score. For an R01, reviewers likely will base the Impact score more on Environment and Approach, whereas an R21 Impact generally should depend more upon Innovation and Significance.

REMEMBER:

There is no magic formula reviewers use to equate your individual criterion scores to your Overall Impact score.

Integrate Impact Throughout

There is no template for incorporating Overall Impact into your grant application. For example, there is no section called "Overall Impact," and NIH does not incentivize investigators to add a paragraph labeled as such to their proposals. Instead, the agency's Office of Extramural Research indicates that applicants should describe impact clearly in whatever words are relevant to their proposed projects.

Some reviewers state that the impact should "bubble up" throughout the entire application. Others note that you should integrate it so that your Approach supports your Specific Aims, indicating that you will obtain useful data.

Essentially, reviewers want to see that not only are you addressing a timely and important problem, but also that you can accomplish it in the period outlined with the resources requested. Plus, the information you glean will be useful by the next generation of experiments or possibly be translatable in the near term.

With this in mind, one tactic is to include a simple "impact statement" in each of the five core criteria sections. For example, in the innovation section, you might note how your research will affect future efforts in the field, such as the following:

From NIA sponsored project 1R01AG041955-01A1 Understanding How Personal Networks Change

5. Future Directions

With these panel data available for analysis and the cost-effective web-based methodology established, there will be two foundations on which to build. First, we will have enabled understand the causal relationships behind network change and health. The rich data set will accessible to other social scientists for analysis of personal networks beyond that which has been planned by the Principal Investigator, e. g., on lending practices or the role of pets in health for people living alone. Second, the methodology can be extended to organizational studies using the total network

approach, and have a clearer understanding of how to minimize measurement error. The budget includes the mentoring of an early stage investigator to continue working and developing this project and doing so in ways that incorporate the perspectives of the increasingly important technologically-based social networks as well.

The Project Summary/Abstract is also a good place to indicate your research's impact because it is one of the first elements of your application reviewers will read. For instance, consider the following:

From NHLBI sponsored project 1R01HL114432-01A1 DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES?

Because prior research suggests that resource allocation among parks varies by neighborhood SES, we propose to undertake a national longitudinal study of the existence of disparities in park management practices in 25 representative US cities and 200 parks. In order to advance the state of science on the influence of park management practices on physical activity and park use and to shape public policy on health promotion at the population level, we propose an investigation with the following specific aims: 1) To determine whether there are systematic differences in park resources, programming, management practices, and park use depending upon the socioeconomic status of park neighborhoods in a representative sample of American cities, 2) To determine whether changes in resource allocation among parks in these cities are distributed equally among high and low income parks, or whether allocation changes attempt to address health disparities among potential park users. We will also determine whether changes in resource allocation are accompanied by changes in park-based physical activity, and 3) To make recommendations to the Departments of Parks and Recreation in each city that will support greater use of park facilities among populations who may experience health disparities that can be ameliorated by physical activity.

The second sentence, stating that the project will advance park management science and shape health promotion policy, combined with the phrasing of the

STRATEGY:

One tactic is to include a simple "impact statement" in each of the five core criteria sections.

specific aims, particularly aim 3, clearly indicates the potential impact of the proposed study. Although NIH does not require — or even suggest — that you include such a statement, making your Overall Impact readily accessible for reviewers can support your chances that they will more easily recognize it.

CITE YOUR BIBLIOGRAPHY AND REFERENCES

Direct from NIH:

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application.

Unless otherwise noted in an FOA, this section is required for submissions to NIH and other PHS agencies. This section (formerly "Literature Cited") should include any references cited in the PHS 398 Research Plan form (see Section 5.5 for details on completing that form). When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process." A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material). The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

What this means:

Essentially, NIH reviewers do not want to be inundated with copies of articles that they can review online. So if you refer to published studies or information in your Research Strategy section, then you should cite them in this section. And unless the publication is not available online or is not part of the NIH or Pubmed system, you should not include a copy of it with your application.

If you must include a publication with your application, you should offer it as an appendix rather than including it within the application.

Here is a sample of how your bibliography entries might appear:

1. Kowal J, Tkach M, Théry C. Biogenesis and secretion of exosomes. Curr Opin Cell Biol. 2014 Jun 21;29C:116-125. doi: 10.1016/j.ceb.2014.05.004. [Epub ahead of print] Review. PMID: 24959705 [PubMed - as supplied by publisher]

2. Revenfeld AL, Bæk R, Nielsen MH, Stensballe A, Varming K, Jørgensen M. Diagnostic and Prognostic Potential of Extracellular Vesicles in Peripheral Blood. Clin Ther. 2014 Jun 1;36(6):830-846. doi: 10.1016/j.clinthera.2014.05.008. Review. PMID: 24952934 [PubMed - as supplied by publisher]

3. Lamichhane TN, Sokic S, Schardt JS, Raiker RS, Lin JW, Jay SM. Emerging roles for extracellular vesicles in tissue engineering and regenerative medicine. Tissue Eng Part B Rev. 2014 Jun 23. [Epub ahead of print] PMID: 24957510 [PubMed - as supplied by publisher]

Reviewers highlight that the literature you cite should be from sources respected in your field. This means choosing academic literature from tier 1 and 2 academic journals or reports from IOM and similar sources. Likewise, policy reports should come from nationally recognized think tanks of government entities.

CONCLUSION

Because the Research Strategy section of your application includes the Significance, Innovation and Approach criteria that NIH reviewers will use to evaluate your proposal, you will spend most of your writing time on this material. At the same time, your project's Overall Impact score will likely depend heavily on this material as well.

As if that were not enough pressure, the agency has limited the number of pages you can use for your efforts. Nonetheless, you must demonstrate not only that you have a viable proposal worth funding, but that it is a valuable addition to your scientific field. ■

Your Notes:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Chapter 6:
Special Considerations

When outlining your project, if you plan to use human subjects – or sample or data from them — you must complete the key portions of the application associated with these groups. Protections for human subjects are monitored by your institution through a committee called the Institutional Review Board (IRB). While IRB procedures and rulings can vary from institution to institution, all are following federal government guidelines for protections of human subjects.

The most reliable source for up-to-date and accurate information on the IRB and protections of human subjects is the Office of Human Research Protections (OHRP) in HHS (see http://www.hhs.gov/ohrp/index.html). The OHRP website has links to all relevant legislation and regulations, forms, procedures and guidelines. OHRP is also the entity that regulates local IRB offices and committee and would be the place to ask questions about particular IRB procedure if it appears to violate IRB standards and practices. Research subjects or organizations can also contact OHRP to investigate violations of protections of human subjects. However, most investigations are conducted at the local level by the researcher's IRB office. Most research projects give the local IRB as a contact if subjects have concerns and OHRP will refer complaints to the local IRB to follow up.

Both you and your institution must assure NIH that human subjects will be protected. NIH cannot award any grant until such assurances are on file with the agency. However, you do not have to have IRB approval before your grant is funded. In your application, you want to include enough information to let reviewers know that you understand the need for protection of human subjects and the government laws governing your protection. They will want to know in general how you plan to follow the basic requirements of the IRB, including protecting privacy and confidentiality, understanding the risks your research might have for people involved in the study, informed consent, potential benefits of your research to subjects and the general public, and how data will

be kept secure. For more information on IRB applications, particularly for the social and behavioral sciences, see PIA guide, *Qualitative Research & IRB: A Comprehensive Guide for IRB Forms, Informed Consent, Writing IRB Applications and More* https://principalinvestigators.org/product/qualitative-research-irb/

Include enough information so reviewers will have no questions about what you propose to do. Although you do not need IRB approval when you submit your application, you should begin the approval process early because revisions and final approval can take time. And before NIH can fund your grant application, there must be a Human Subject Assurance on file with the Office of Human Research Protections. This is usually handled at the institutional level.

.

HUMAN SUBJECTS ASSURANCES FOR BEHAVIORAL AND SOCIAL SCIENCE PROJECTS

Most human subjects applications and IRB procedures in the health sciences are designed for biomedical studies and clinical trials. As such, they are primarily designed to address potential physical harm to participants based on their participation in a drug trial or other test that might involve invasive procedures. Physical activity that may cause harm to people with heart conditions, asthma, or other health conditions that put them at risk may also be a concern. Maintaining safety and confidentiality may include the health histories of participants, DNA, blood samples, or any other health information that could compromise the individual's ability to work, get insurance, etc., may be a major concern. If you are doing a multi-methods study that also includes biomedical research on human subjects, physical activity, or clinical studies, your project may need to address human subjects concerns related to these kinds of human subjects protection.

However, most social and behavioral science research involves a different kind of risk. Participants in psychological studies may be put in stressful situations or asked to share information from traumatic events. Studies that observe activities that may be illegal (for example drug use, vandalism, or underage drinking) could also put their participants at risk if the authorities found out. Youth engaged in pre-marital sex may be at risk of physical or mental harm from parents or guardians. Studies of caregivers of infirm elderly or people with disabilities might witness abuse and need to report it. A simple collection of a health history could cause harm if information about chronic illnesses is revealed to insurance companies or employers. Reviewers will want to know that you have thought through the potential risks and rewards of your research and the precautions you plan to take to protect the human subjects in your study.

The two key concepts you need to clarify in the human subjects sections of your proposal are 1) kinds of private or confidential information collected by the study and 2) the level of risk of harm your study would involve for participants. Ideally, your study has procedures in place to protect private information and it will incur minimal risk for participants. Figure six defines these core concepts.

Figure 6: Key Definitions for Human Subjects Protections

Key IRB definitions (from federal law)

- *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable …to constitute research involving human subjects.

- *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Informed consent is one of the centerpieces of human subjects protections. It comes out of the many research horror stories of people who participated in research without their knowledge or consent. As outlined in Figure seven *Elements of Informed Consent*, informed consent means that the subjects understand that their participation is voluntary, that their privacy will be protected, any risks involved in the study and what the researchers intend to do to mitigate risk, how the research will be used, and who they can contact if they have questions or concerns. Informed consent must be obtained from either subjects themselves, or in the case of people unable to make their own decisions, their parents or guardians. IRB protocols are careful to stipulate that populations that could be easily manipulated because they are institutionalized or mentally incapable of making important decisions receive special protections. Those populations are outlined later in this chapter.

Figure 7: Elements of Informed Consent

- Ensuring that participants know:

  > they are voluntary participants in a study

  > their privacy will be maintained

  > how you plan to carry out your research

  > why you are doing this project

  > how the information you gather will be used

- Information on who to contact for additional information on the study

- Information on who to contact if the participant has concerns about how the research is being conducted (usually a center director or sponsored research official)

These elements boil down to three major principles: 1) voluntary participation, 2) assurance that the study will do no harm by protecting privacy and the persons involved, 3) information on how data will be used to contribute to the common good. Voluntary participation involves clearly understanding that a person can both choose not to participate and choose to stop participating in a study part way through if they are uncomfortable with it.

One key aspect of ethical research is ensuring minimal risk. Minimal risk means that the people participating will not experience any more risk to themselves than they would ordinarily encounter in daily life. For example, someone interviewed for a study might be troubled by something it brings up, but the same subject may come up in a conversation. People participating in an observation study of physical activity may overexert themselves and strain their muscles, but they could also do so if they were exercising on their own.

If the study potentially causes more than minimal risk, the researcher needs to show how that the end result justifies additional risk. For example, someone

participating in a drug trial may experience side effects beyond what may occur in an already tested drug, but the benefits of the new drug may outweigh that risk. The researcher also needs to show that safeguards are in place to alleviate symptoms if they occur and will immediately stop the study if more than a few people experience severe side effects. In a qualitative study, participants may be asked to talk about traumatic experiences that they would ordinarily not discuss outside of therapy. The researcher needs to show how asking people to relive trauma will benefit either this population or others in a substantial way. The research team also needs to provide therapy or other appropriate care if a person is further traumatized by the project or has other symptoms caused by the research.

Maintaining privacy and minimizing risk can mean several things. First and foremost, it means that the identity of research participants will not be revealed for any reason without their permission. The only time confidentiality can be broken is if someone reports that they have been abused or harmed by a caregiver or other responsible party. In this instance, researchers are required to inform child protective services or agencies responsible for the elderly and disabled if they suspect abuse while conducting research.

Privacy and minimal risk means more than making sure that a person is not physically harmed. Research protocols also cover psychological damage as well as financial injury or any activity that damages reputation, career or other aspects of life. For example, revealing that someone AIDS could damage their social standing, chances of promotion or ability to get a job. For this reason, researchers are taught not to reveal data to anyone without specific permission.

Participants also have a right to know how their data will be used. Will it be part of an aggregate report or might you use specific examples? How can the study benefit them personally or others? This section also justifies why you are doing the study and explains how it will benefit others. Developing an explanation that shows how your research could improve the lives of people like the study participants is an important part of obtaining informed consent.

Figure 8: Levels of IRB Review

Exempt: Study is exempt from IRB approval due to the nature of the research. Requires brief description of project and justification of exemption.

Expedited: Study requires IRB approval but does not cause more than minimal risk. Requires short description of the project, justification of minimal risk, discussion of informed consent and confidentiality, and copies of research protocols and consent forms.

Full review: Study will create more than minimal risk or involves special vulnerable populations. Requires detailed description of study and potential risks, justification for risks and ways to mitigate them, as well as more detailed materials similar to an expedited application.

The level of IRB review depends on the research methods, the topic of the research, the amount of risk to human subjects, and the nature of the population studied. Research that does not involve currently living human subjects does not require IRB review, but the researcher may need to justify an exemption. Studies that do not involve specially protected vulnerable populations or do not cause more than minimal risk to participants generally require a brief IRB application and are reviewed quickly under the expedited category. Research that may risk the health or wellbeing of participants or involves vulnerable populations will require full review. Full review requires a detailed application and may involve much back and forth between the IRB committee and researcher before the committee is satisfied that the research is justified and any risks mitigated appropriately.

Figure 9: Exempt Categories (from the Common Rule)

- Research on organizations, not individuals
- Research in schools or other educational settings (including special ed) or evaluations of curricula, educational tests or other educational interventions
- Research using data already collected by others if sources publically available or subjects de-identified
- Research on public benefit programs
- Food taste and quality evaluations (as long as food doesn't contain harmful substances)

In general, research that does not include living human subjects is exempt from IRB review. This would necessarily include historical research once sufficient time has passed to not cause undue harm to its subjects or their descendants. Research in public places like observations of public health educational events at a resource fair open to the public or behavior in a public park is exempt given that people are not identified. Any research on organizations is also exempt. For example, studies comparing various kinds of urgent care clinics on organizational characteristics would not require IRB approval. Studies of medical office procedure would also be exempt. In both cases, the researcher would need to obtain approval from the organization to do the research, but would not need IRB approval.

That said, IRB interpretation of the exemption for organizations can be tricky. In one case, an IRB committee insisted that a study of organizations that clearly met the exempt category required expedited review because we were interviewing people to learn about the organization. The IRB staff reasoned that any interview necessarily included a human subject even if they were not the subject of the interview. The project ended up submitting an expedited application.

The other types of research that most obviously are exempt include studies of data that does not identify participants or involves other forms of secondary

sources. Deidentified Medicaid records, public health statistics, and deidentified statistics on the incidence of a particular illness in a state or locality would be examples of datasets that would be exempt from IRB approval. This would also include surveys conducted by others or administrative data where identifying information is removed before it is sent to the researcher. Types of identifying information are covered in the Privacy Act and HIPAA, and researchers should consult these sources when requesting these kinds of data. Generally, privacy information includes names, specific addresses, dates of birth, social security numbers or other commonly used identifiers, but HIPAA and the Privacy law may include other information.

Figure 10: Categories for Expedited Review (from the Common Rule)

- Some or all of the research methods are found by the reviewer(s) to involve no more than minimal risk
- Minor changes in previously approved research during the period (of one year or less) for which approval is needed

---

Unless they involve vulnerable populations, most other behavioral and social science research will fall under the expedited review category. Figure ten provides information on what kinds of studies fall into this category. Regardless of how much risk you think you application may involve, you will need to identify in your R01 application the level of review you think should be involved for your study and respond to the general questions you will answer in more detail for your institution's IRB should your project be funded.

INFORMING REVIEWERS ABOUT HUMAN SUBJECTS

Direct from NIH:

Early on NIH's application, you must indicate whether your proposal involves using human subjects. If it does, you must later upload several separate documents indicating who will be involved, why, how they will be impacted and your rationale for including them.

In fact, there are four such documents you must prepare:

- Protection of Human Subjects
- Inclusion of Women and Minorities
- Targeted/Planned Enrollment Table
- Inclusion of Children

NIH does not place any page count restrictions on these, but it states that you should "be succinct." Do not use this section to circumvent the Research Strategy section's page limit.

Each of these documents must include specific information regarding the human subjects, and we will look at them individually.

Protection of Human Subjects

This portion contains at least four sections, and NIH suggests you use subheads to delineate them. Further, if your research includes a clinical trial, you should have an additional subheading, "Data and Safety Monitoring Plan," which we will discuss next.

Direct from NIH:

REMEMBER:

NIH does not place any page count restrictions on the human subjects documents, but it states that you should "be succinct."

4.11 Risks to Human Subjects

a.   Human Subjects Involvement, Characteristics, and Design

- Describe the proposed involvement of human subjects in the work outlined in the Research Strategy section.

- Describe and justify the characteristics of the subject population, including their anticipated number, age range, and health status if relevant.

- Describe and justify the sampling plan, as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any subpopulation.

- Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.

- If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, describe and justify the selection of an intervention's dose, frequency, and administration.

- List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected.

b.   Sources of Materials

- Describe the research material obtained from living individuals in the form of specimens, records, or data.

- Describe any data that will be collected from human subjects for the project(s) described in the application.

- Indicate who will have access to individually identifiable private information about human subjects.

- Provide information about how the specimens, records, and/or data are collected, managed, and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed research project.

c.   Potential Risks

• Describe the potential risks to subjects (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects.

• Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research.

What this means:

Section 1: Risks to Human Subjects. When you write this section, NIH suggests that you break it up into three components:

Section 1A: Human Subjects Involvement, Characteristics and Design.

According to NIH, you should use this section to describe and justify the following:

• The proposed involvement of human subjects in the work outlined in your Research Strategy section.

• The characteristics of the subject population, including their anticipated numbers, age range and health status if relevant.

• The sampling plan, as well as the recruitment and retention strategies and the criteria for including or excluding any subpopulation.

• The rationale for involving special vulnerable populations, such as fetuses, neonates, pregnant women, children, adults that do not have the mental capacity to make decisions for themselves (for example people with dementia or developmental disabilities), prisoners or institutionalized individuals.

• If relevant, the procedures for assigning individuals to a study group, including selecting who receives a particular intervention.

• Any collaborating sites where human subjects research will be performed and the role of those sites and collaborating investigators in performing the

proposed research, including how data from the site(s) will be obtained, managed and protected.

Section 1B: Sources of Materials. For this section, indicate the following:

- The research material obtained from living individuals, such as specimens, records or data.
- Any data that will be collected from human subjects for the project(s) described in the application.
- Who will have access to individually identifiable private information about human subjects.
- How the specimens, records and/or data are collected, managed and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed project.

Section 1C: Potential Risks. Here, you must detail the following:

- The potential risks to subjects — physical, psychological, financial, legal or other — and their likelihood and seriousness to the human subjects.
- Where appropriate, any alternative treatments and procedures, including any risks and potential benefits, to participants in the proposed research.

For example, this section might read as follows:

From NHLBI sponsored project 1R01HL114432-01A1 DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES?

HUMAN SUBJECTS

The **majority of the** study will be exempt from human subjects review since we are not recruiting any subjects but only passively observing their behavior in public settings. Likewise, previous IRB reviews of our protocol for interviewing park staff about administrative policies have also been deemed exempt, since no personal information is collected and only administrative data are sought. The key stakeholder component may be subject to IRB review.

Human Subjects Involvement and Characteristics:

- **Characteristics of the Subject Population.** The subjects will be adult key stakeholders in 25 communities (n=125) who would be knowledgeable about parks in their communities and hold leadership positions.
- **Sources of Materials:** Interviews
- **Potential Risks:** There are minimal risks since we will be asking about community level information. However, sometimes opinions can be shared that may have some political repercussions. Risks are related to breaches in confidentiality for subjects that provide critical comments.
- **Adequacy of Protection against Risks:** All subjects invited for interview will be told that this part of a research project. We will not identify who participated in the interviews, or publish the results in a way so that individuals can be identified, but will use the information to interpret our objective findings.

- Recruitment and Informed Consent: Subjects will beasked to provide verbal consent to avoid linking their name with the interview material.
- Protection Against Risk: All data will be stored on password protected computers with access limited to project staff.

c. Potential Benefits of the Proposed Research to the Subjects and Others

Participants will receive no direct benefit. No incentive is being offered, since the interview will be relatively short, and is in line with civic orientation of the key stakeholders. The benefit to society in general is the improvement of health and well-being, by eventually identifying the park policies that optimize park use and park-based physical activity.

d. Importance of the Knowledge to be Gained- This study will help optimize the use of available community resources that promote health and fitness, facilities that are currently underutilized.

Data Safety and Monitoring: All materials will be stored with no identifying information linked to the research material.

Data Safety and Monitoring Plan: This is primarily an observational study of public behaviors and one that assesses administrative practices. Nevertheless, we will use password protected computers and make sure the names of key stakeholders are not linked to the interview data to protect confidentiality.

Direct from NIH:

1.1.2 Adequacy of Protection Against Risks

a. Recruitment and Informed Consent

• Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.

• Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent document(s) need not be submitted to the PHS agencies unless requested.

b. Protections Against Risk

• Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.

• Research involving vulnerable populations, as described in the DHHS regulations, Subparts B-D must include additional protections. Refer to DHHS regulations, and OHRP guidance:

• Additional Protections for Pregnant Women, Human Fetuses and Neonates: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb

• Additional Protections for Prisoners: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc

• OHRP Subpart C Guidance: http://www.hhs.gov/ohrp/policy/index.html Additional Protections for Children: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd

- OHRP Subpart D Guidance: hhs.gov/ohrp/policy/populations/children.html
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a general description of the plan for data and safety monitoring of clinical trials and adverse event reporting to the IRB, the NIH and others, as appropriate, to ensure the safety of subjects.

What this means:

Section 2: Adequacy of Protection Against Risks. For this area of the document, NIH outlines these two sections:

Section 2A: Recruitment and Informed Consent. Here, provide the following information:
- Plans for recruiting subjects (where appropriate) and the process for obtaining informed consent. If your project will use children, outline the process for meeting parental consent and child assent requirements.
- The circumstances under which you will seek and obtain consent, who will seek it, what information you will provide to prospective subjects and how you will document consent. If you will seek a waiver of some or all of the informed consent elements, provide justification for the waiver.

Section 2B: Protections Against Risk. In this section, NIH states that you should include the following:

- Planned procedures for protecting against or minimizing potential risks, including risks to the privacy of individuals or confidentiality of data, and assess their likely effectiveness.
- Research involving vulnerable populations.
- Additional protections for pregnant women, human fetuses and neonates.
- Additional protections for prisoners.

- Additional protections for children.
- When appropriate, plans for ensuring necessary medical or professional intervention if subjects suffer an adverse effect. If your proposal involves a clinical trial(s) — such as biomedical or behavioral intervention studies – you must include a general description of the plan for data and safety monitoring of clinical trials and adverse event reporting to the appropriate organization(s) to ensure the subjects' safety.

This section should include both the potential risks and ways that you plan to mitigate risk. For example, if your study involves physical activity, will you have someone with medical training on staff in case of an unexpected health emergency? Will you have defibrillator, etc.?

Here's an example of how this section might read:

From NIDA sponsored project 1R01DA034072-01A1 SUBSTANCE USE IN RESERVISTS SOCIAL AND ENVIRONMENTAL INFLUENCES

Consent Procedures

Both wife and husband will provide consent at the first in-person assessment. Wives and husbands will be told about the purposes of the research, the time and effort involved, and the procedures. This information will be provided in writing on a consent form at the time of the assessment. Consent will be obtained in a noncoercive fashion. Each participant will be provided with a copy of the consent form. S/he will be asked to silently read from the consent form while a member of the research staff reads it aloud. At the end of this reading, the staff person will solicit and answer questions related to the material presented in the consent form. When these questions have been answered to the subject's satisfaction, s/he will be asked to sign two copies of the form. The staff-person also will sign the consent form. One copy of the signed consent form will be kept by the staff and one copy will be given to the subject.

Potential Risks and Precautions

There are several possible human subject risks involved in this study. The most important risk concerns maintenance of the confidentiality of participation and particularly acknowledgement of substance use and health behaviors. We will protect the confidentiality of the survey responses by pre-coding the computerized surveys and maintaining a master list in a password protected file. Data will be stored in password protected computer files that can only be viewed by the project staff. All other data is also stored in password protected files. Identifying information is separated from the raw data, and an ID number links participant identity to the data. The master list linking ID numbers and subjects is maintained in a separate computer with a different password protection. This list would be accessible only to designated project staff.

There are a variety of risks pertaining to other aspects of the assessment. Because this research assesses marital behavior, we will learn of husband and wife aggressive behavior. We will provide information regarding counseling and shelters to all participants and inform them because of the sensitive nature of some of the questions we are providing resource lists to everyone. Because it is possible that participants may move away from western New York during the course of the study, the resource list will include the toll free number and website for the National Domestic Violence Hotline--an agency that can provide local resources to individuals. To further protect the participants, we interview men and women separately. For participants who move away, we will ask them to complete they survey using a web based data collection system. Given that we are assessing one year time periods, there is some flexibility on completion dates for each survey; this flexibility will help to ensure that participants can complete the assessment in a private location. If, however, a participant completing the survey needs to quickly leave the current page (for example, because his/her partner enters the room), there will be a quick escape button on each screen that will automatically take the participants to a 'safe site' such as news or weather website. This approach is commonly used on domestic violence websites both locally in Western New York as well as on the National Domestic Violence Hotline website. It is also important

to note that because we are assessing past year behaviors, we will not have information on imminent danger. Further research staff (and not medical staff) will be interacting with all participants, therefore, in New York (and elsewhere) there is no reporting requiring for competent adult victims of domestic violence (National Center for the Prosecution of Violence Against Women). Web based assessments, in fact web-based interventions for substance use and PTSD have recently been successfully administered to VA populations. [53]

Another risk concerns the reactions of the participants to completing questionnaires delving into personal aspects of their life and family. As in nearly all psychological studies, completing these questionnaires may be a source of discomfort to some participants. As in our previous research, participants will be informed that they may refrain from answering any questions that are of concern and may withdraw from the study at any time without penalty. Our experience to date leads us to judge this risk as minimal.

A related issue concerns the possibility that our assessment would uncover substance use disorders that would necessitate treatment. Our approach in other research with community samples has been to focus not on the diagnosis per se, but rather on evidence of the potential for serious injuries or health impairment. If there is an indication of a problem with alcohol or drug abuse or psychiatric problems, the participant will be excused from participating, and if warranted will receive a referral to a local mental health and/or substance abuse treatment facility, including at the University at B's Research Institute on Addictions, Clinical Research Center, a no-cost New York State licensed treatment facility for alcohol and substance abuse problems. Reports of adverse events will be made to the University at B's Institutional Review Board. Because we promise participants that their responses will be held in confidence with respect to their spouse, we provide such individuals brief feedback and referral in the context of an individually-oriented debriefing. We will include this procedure in our current project, with a direct linkage between the computer-administered questionnaires and an email alert to the research technician who is conducting the procedures.

Because of the computer-based nature of the interview, the likelihood of uncovering instances of danger to oneself or to others is very remote. We do inform the participants in the consent form that confidentiality of information that represents a danger to themselves or others cannot be guaranteed, although the questionnaires do not include any such questions, and the computer-based nature of the assessment does not provide participants with the opportunity to offer such information. If, for any reason, information regarding the potential for suicide, violent behavior, or child abuse were to emerge standard policies have been developed to address these issues, and an Emergency Response Team (ERT) is available for consultation. The research technicians involved in this study will be trained on policies and procedures. These procedures include immediate notification of the project director or Pl, and the convening of the project leadership while the participant is still on site. The project leadership includes a New York state licensed clinical psychologist. Additionally, the Pl is the Assistant Sector Leader of the Emergency Mental Health Component of the County's Specialized Medical Assistance Response Team. As such, he has training and expertise in crisis intervention. Our procedures provide a structure for immediate, rather than delayed, advice from colleagues with expertise and experience in addressing these issues.

Direct from NIH:

4.1.3 Potential Benefits of the Proposed Research to Human Subjects and Others

- Discuss the potential benefits of the research to research participants and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

What this means:

Section 3: Potential Benefits of the Proposed Research to Human Subjects and Others. For this section, you should provide the following information:

- The potential benefits of the research, not only to participating human subjects, but also to others.
- Why the risks to subjects are reasonable compared to the anticipated benefits to research participants and others.

This section might read as follows:

From NIDA sponsored project 1R01DA034072-01A1 SUBSTANCE USE IN RESERVISTS SOCIAL AND ENVIRONMENTAL INFLUENCES

Potential Benefits to Subjects and Society

The vast majority of the couples participating in this study are not expected to have any adverse reactions to any of the study procedures, which are widely used and well established. For some couples, having access to information about community services directed at facilitating family well-being may be invaluable. The project's aim to determine influences on adult substance use, and the impact of substance use on relationships can inform current prevention and intervention approaches. Given these potential benefits and the minimal risks associated with the procedures, the cost/benefit ratio is very favorable.

Direct from NIH:

4.1.4 Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

What this means:

Section 4: Importance of the Knowledge to Be Gained. For this portion, NIH states that you should provide details regarding the following:

- The importance of the knowledge gained or to be gained as a result of the proposed research.
- Why the risks to subjects are reasonable when compared to the importance of the expected resulting knowledge.

The following is an example of this section:

From NIA sponsored project 1R01AG041955-01A1 Understanding How Personal Networks Change

5.g. Importance of the Knowledge to be Gained. The medical and public health communities have come to focus on how important people's personal networks are for maintenance of health. Social support is now considered a major positive factor and its absence a major risk factor in physical as well as mental health. But researchers do not understand well how people's support networks change, how they respond to life shocks, and what the health consequences of such changes are. The proposed study will provide the first prospective and systematic information regarding the dynamics of personal networks. Furthermore, unlike other studies, we will be truly able to examine the effects of retirement, residential mobility, illness, widowhood and other changes to social networks, and the subsequent impacts on health and well-being.

Direct from NIH:

4.1.5 Data and Safety Monitoring Plan

The NIH Data and Safety Monitoring Plan Policy is described and referenced in Section 5.3.

- If the proposed research includes a clinical trial, create a heading entitled "Data and Safety Monitoring Plan."
- Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring. Describe the entity that will be responsible for monitoring and the process by which Adverse Events (AEs) will be reported to the Institutional Review Board (IRB), the funding I/C, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations. Be succinct. Contact the FDA (http://www.fda.gov/) and also see the following websites for more information related to IND and IDE requirements: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312 (IND), http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812 (IDE).
- The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:
  a. PD/PI (required)
  b. Institutional Review Board (IRB) (required)
  c. Independent individual/safety officer
  d. Designated medical monitor
  e. Internal Committee or Board with explicit guidelines
  f. Data and Safety Monitoring Board (DSMB). NIH specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for multi- site clinical trials involving

interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials may also need DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.

- A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects. For additional guidance on creating this Plan, see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html.

What this means:

Potential Section 5: Data and Safety Monitoring Plan. As stated earlier, if your proposal includes a clinical trial, NIH states that you must include a section with this subheading.

You should provide the following details in this section:

- A general description of your monitoring plan for data and safety. Describe the entity responsible for monitoring and the process by which adverse events (AEs) will be reported to your institutional review board (IRB), the funding ICO, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations.
- The frequency of monitoring will depend on potential risks, complexity and the trial's nature. Therefore, you will have a number of options regarding monitoring trials, which can include, but should not be limited to, monitoring by a:
  a. PD/PI (required)
  b. IRB (required)

  c. Independent individual/safety officer

  d. Designated medical monitor

  e. Internal committee or board with explicit guidelines

  f. Data and Safety Monitoring Board (DSMB). In fact, NIH specifically requires establishing DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials may also need DSMBs, smaller clinical trials may not require them, and alternative monitoring plans may be appropriate.

- You must submit a detailed Data and Safety Monitoring Plan to your IRB and subsequently to the funding ICO for approval prior to accruing human subjects.

If your study is attached to a biomedical study or is a clinical trial, you will need to follow NIH's guidelines for data monitoring closely in your proposal. If your data is the standard kinds of data collected by behavioral and social science projects, you will need to make fewer formal precautions to monitor your data. Nevertheless, in any project where you have interviewers from any source, you will need to ensure that they are trained in keeping information confidential, storing it in a secured place if they are collecting data at another site or people's homes, and maintaining security for data at the central repository for that data.

For instance, this section might read as follows:

From NIA sponsored project 1R01AG041955-01A1 Understanding How Personal Networks Change

5.e. Adequacy of Procedures for Protecting against Risks. The other principal area of concern relates to confidentiality of data that is collected. Subjects will be reminded of the confidentiality of their responses, that we will use code numbers rather than names to identify participants, and that this information will not be made available to persons outside the team of investigators. Both RESEARCH COMPANY C and Research Firm B implement a number of policies and procedures to ensure respondent confidentiality, certified by NIH and consistent with HIPPA rules. All Research Firm B interviewers working on the project will have signed a confidentiality statement as part of their employment contract and will be assigned individual computer user codes with encrypted passwords. All interviewers undergo a criminal check, and will have two forms of ID and a uniform attire (logo shirt of Research Firm B). Address, telephone numbers and other personal identifiers will be purged from data files at Research Firm B, and replaced with case identification numbers, after interviewing and data processing work has been completed. Access to the key linking the information is highly restricted. As this is a prospective cohort study the research staff at UC A will maintain contact information and the ability to link information from each source of data and from each wave, including the survey data that will be sent by Research Firm B. Original data will be split into two files: one with the personal identifiers and key codes so that individual information cannot be identified, and the other with the data and the key codes. Each file will be stored separately, and the file with the personal identifiers will be locked. All files for data analysis will be kept on secured servers shielded from unauthorized access by firewalls and password protected. Furthermore, no individuals will be identified in any publication.

Direct from NIH:

4.1.6 ClinicalTrials.gov Requirements

Public Law 110-85 (also known as the FDA Amendments Act (FDAAA) of 2007) mandates registration and results reporting of "applicable clinical trials" in ClinicalTrials.gov. Under the statute these trials generally include: (1) Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and (2) Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance. Review the statutory definition of applicable clinical trial to identify if registration is required to comply with the law (See PL 110-85, Section 801(a), adding new 42 U.S.C. 282(j)(1)(A)).

NIH encourages registration of ALL clinical trials whether required under the law or not.

Registration is accomplished at the ClinicalTrials.gov Protocol Registration System Information Website (http://XXXinfo.clinicaltrials.gov/). A unique identifier called an NCT number, or ClinicalTrials.gov registry number, will be generated during the registration process.

The NIH implementation of FDAAA requires:

- the registration of applicable clinical trials in ClinicalTrials.gov no later than 21 days after the first subject is enrolled,
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA, and

- if an "applicable clinical trial" is funded in whole or in part by an NIH grant or cooperative agreement, grant and progress report forms shall include a certification that the responsible party has made all required submissions to ClinicalTrials.gov.

For competing (new and renewal) applications that include applicable clinical trials which require registration and results reporting under FDAAA, provide the NCT number/s, Brief Title/s (protocol title intended for the lay public – see Definitions), and the identity (name, organization) of the responsible party and their contact information (e-mail address is required for internal administrative use only) in the human subjects section of the Research Plan under a section heading entitled ClinicalTrials.gov. If a new applicable clinical trial is proposed, or if the grant will support an applicable clinical trial that is ongoing but not yet required to register under FDAAA (e.g. less than 21 days have passed since enrollment of the first patient), the human subjects section of the Research Plan must include a clear statement, under the heading ClinicalTrials.gov, that the project includes an applicable clinical trial which will require registration in ClinicalTrials.gov.

The entity responsible for registering the trial is the "responsible party". The statute defines the responsible party as:

1. the sponsor of the clinical trial (as defined in 21 C.F.R. 50.3) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.3), or
2. the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee (provided that "the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements" for submitting information under the law) (http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf). See PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(ix)).

For the complete statutory definitions of "responsible party" and "applicable clinical trial", refer to Elaboration of Definitions of Responsible Party and Applicable Clinical Trial.

The signature on the application of the Authorized Organization Representative assures compliance with FDAAA.

Additional information can be found on the ClinicalTrials.gov Web site (http://grants.nih.gov/ClinicalTrials_fdaaa).

What this means:

Potential Section 6: ClinicalTrials.gov Requirements.

If your application includes applicable clinical trials that require registration and results reporting under the FDA Amendments Act of 2007 (FDAAA, Public Law 110-85), you should include this section to provide the ClinicalTrials.gov registry number(s) (NCT), Brief Title(s) (which is the protocol title intended for the lay public), and the identity (name and/or organization) and contact information for the responsible party. If your proposal includes a new clinical trial or if the grant will support an applicable clinical trial that is ongoing but not yet required to register under FDAAA (that is, less than 21 days have passed since enrolling the first patient), you must clearly state in this section that the project includes an applicable clinical trial that will require registration in ClinicalTrials.gov. NIH further states that the entity responsible for registering the trial — the "responsible party" — is one of the following:

• The sponsor of the clinical trial, or
• The PI of such clinical trial if so designated by a sponsor, grantee, contractor or awardee — as long as the PI "is responsible for conducting the trial, has access to and ability to meet all of the requirements" for submitting information under the FDAAA.

The following is a human subjects section from a social and behavioral science clinical trial:

From NIAAA sponsored project 1R01AA021136-01A1 A RANDOMIZED CLINICAL TRIAL OF CULTURALLY TAILORED MI

1. Risks to the Subjects
Protections for Human Subjects

Human Subjects Involvement and Characteristics. For the Randomized controlled trial, a total of 357 Latino males and females, 18-65 years old who are hazardous drinkers, will be recruited. A total of 357 in the randomized trial are required for the study. (With 80% retention during follow-up, we should start with 250 participants who receive random assignment to treatment condition (the intent to treat sample) and initially assess 357 participants to allow for 30% attrition from recruitment). Potential participants will be excluded if they manifest cognitive impairment or psychotic symptoms, as detected by recruitment requests. The Community Health Center, located in Boston, MA, will serve as the main study site where participants will receive baseline assessments and interventions. Follow-up calls will also be made from the CHC, as well as from Northeastern University. Study recruitment activities will be conducted at CHC and in the community. CHC serves up to 11,000 patients a year, approximately 62% are Latino. According to 2005- 2009 Census Data for the City of Boston, 15.7% are Latino. More than half are from the Caribbean (53%, 30.1% from Puerto Rico and 22.47% from the Dominican Republic), and the remainder is Salvadoran (9.3%), Colombian (8.1%), and Mexican (6.5%).

Sources of materials. Participants will be the sole source of data for the study and all data will be obtained specifically for research purposes. Data sources include participant responses to questionnaires and audiotaping of the intervention.

Potential Risks. The risks in this study are considered minimal and include subjective discomfort from answering questions related to alcohol consumption and consequences, and risks of breach of confidentiality. The likelihood of experiencing subjective discomfort is very low, as it is very rare that participants have expressed discomfort or concern about answering questions related to alcohol consumption or consequences. Participants will be asked to take a breathalyzer test prior to any study contacts. They will be told that if the breathalyzer results register more than .00, that they will be asked to return for a later meeting. It will be explained that this information is collected to ensure that participants are not intoxicated during study activities, and that the results will be kept confidential. A Data Safety and Monitoring Plan details the plan for overseeing data safety and monitoring, reporting of adverse events, and ensures that participant risk does not outweigh study benefits.

1. Adequacy of Protection Against Risks

Recruitment and Informed Consent. Participants will learn about the study through recruitment publicity (ie, radio advertisements, flyers) at the CHC or in the community. Interested participants will be approached by study staff or will be asked to contact study staff, who will then screen them for eligibility. If eligible, study staff will schedule a meeting for the participant. At this meeting, the study will be explained, and written informed consent (in Spanish or English) will be obtained prior to participation. All participants will be fully informed of study purposes and procedures, potential risks and benefits, confidentiality, and the Privacy Rule. It will be made clear that all information obtained during study conduct will be confidential and used solely for research purposes. Each participant will be given a copy of the consent and an original will be kept in a locked file. Audiotapes of the intervention will be used for training and research purposes only and will be kept locked. Selected segments of the audiotapes, or their transcription, will be used for presentation at research conferences. With participant permission, excerpts from material may be used for presentation at research conferences with the identity disguised.

Protection against risk. Risks in this study are considered minimal. To address potential discomfort, participants will be told they do not have to respond to questions if they do not wish to. If they do not wish to be taped they will not be taped, and they will be allowed to participate or to withdraw from their study if they choose. To address potential breaches of confidentiality, participants will be told in advance that the intervention will be taped prior to the intervention and that resulting data will be used solely for research purposes and will be kept in a locked cabinet. They will be told that breathalyzer results will only be used to determine that they are not intoxicated at the time of study contact, and results will be treated as anonymous. Participant responses to questionnaires and their breathalyzer results will be numerically coded, and all identifying information will be separated from study data. In no way will identities be linked to study data. Data will be kept in locked file drawers and password protected computer files. If in the course of the research interview a participant discloses a desire to hurt him/herself or others, participants will be told that this information will be shared with medical authorities. If a participant reveals substantial mental health problems, or if this information is revealed in the assessment, appropriate referral for psychological intervention will be arranged by the PI. All information collected as part of the study will be available only to the research team and the PI. No names will be used in presenting data in lectures, seminars, and papers, and data will be presented in aggregate form. Information will be released only with participant written consent. Participants will be given full access to their data and professional interpretation will be provided if requested after study completion. The Community Advisory Board will also assist in interpreting results and will be available as requested to explain study findings with participants.

Potential benefits of the proposed research to the participants and others. Participants may benefit from the opportunity to learn more about the effects of alcohol. Participants receiving interventions in both conditions will receive some feedback on his/her alcohol consumption, as well as suggested strategies to decrease alcohol consumption if interested. If interested, all participants will receive information about referral sources, including treatment centers and resources to support sobriety.

Importance of the Knowledge to be gained. Given the lack of treatment services to this population and the disproportionate levels of negative consequences related to drinking, the potential benefits of providing needed information about heavy drinking outweigh potential risks. In particular, health related information on the consequences of long-term drinking, and the information on blood alcohol levels and drinking and driving, may be particularly beneficial. The risks to participants are reasonable in relation to the importance of the knowledge that may be gained, and in relation to need information to be disseminated in the Latino community. It is also helped that study findings may be used to inform health policy, such as including training in motivational interviewing at community agencies.

Data Safety and Monitoring Plan. Standard procedures will be followed to monitor the safety of study data. The PI and research team will meet weekly to discuss study progress, review data quality, participant recruitment, study retention, and examine other factors that may affect outcome or participant risk. They will also meet to discuss, if necessary, any concerns about a particular participant or any problems that may arise for participants. If necessary, changes will be made to protocol. A brief report based on this review will be submitted quarterly to Brown University's Institutional Review Board. The PI will conduct daily oversight of participant safety. She will meet weekly with the Project Coordinator and the research assistants to review participant progress and their experience with study procedures, including adverse events. Participants will be seen a total of 4 times over a period of 12 months, and any adverse events, including serious adverse events, will be reported to the Northeastern IRB immediately by phone or by written report 24 hours after receipt of information regarding the event by the PI. The Principal Investigator will inform NIH of any significant action taken as a result of this report.

Inclusion of Women and Minorities

For this Human Subjects document, you must address NIH's policy that all agency-supported biomedical and behavioral clinical research projects must include women and members of minority groups and their subpopulations unless a clear and compelling rationale and justification that including them is inappropriate with respect to the subjects' health or the research's purpose.

Direct from NIH:

4.2 Inclusion of Women and Minorities

In the attachment for Item 7, include a heading entitled "Inclusion of Women and Minorities." Although no specific page limitation applies to this section of the application, be succinct. The NIH Policy on the Inclusion of Women and Minorities in Clinical Research is described and referenced in Section 5.6.

Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the inclusion of women and minorities in clinical research.

In this section of the Research Plan, address, at a minimum, the following four points:

1. The targeted/planned distribution of subjects by sex/gender and racial/ ethnic groups for each proposed study or protocol using the format in the Targeted/Planned Enrollment Table. (Instructions for completing this table are provided below in 4.3.) If using existing specimens and/or data without access to information on the distribution of women and minorities, so state and explain the impact on the goals of the research as part of the rationale that inclusion cannot be described (item 3 below). Alternatively, describe the gender and minority composition of the population base from whom

the specimens and/or data will be obtained. Include the Targeted/Planned Enrollment Tables in this section.

2. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.

3. A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group (see examples below).

4. A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

4.2.1 Additional Instructions and Requirements When NIH-Defined Phase III Clinical Trials Are Proposed

If the proposed research includes an NIH-Defined Phase III Clinical Trial, the section on Inclusion of Women and Minorities also must address whether clinically important sex/gender and/or race/ethnicity differences are expected from the intervention effect. The discussion may include supporting evidence and/or data derived from animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology and other relevant studies. The discussion of expected sex/gender and/or race/ethnicity differences in intervention effect must include selection and discussion of one of the following analysis plans:

• Plans to conduct valid analyses to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, or

• Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups. (Representation of sex/gender

and racial/ethnic groups is not required as subject selection criteria, but inclusion is encouraged.), or

- Plans to conduct valid analyses of the intervention effect in sex/gender and/ or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect among subgroups.

What this means:

Cost is not an acceptable reason for excluding women or minorities except when the study would duplicate data from other sources, NIH states.

Consequently, Scientific Review Groups (SRGs) — also known as "study sections" — will assess your application as being acceptable or unacceptable regarding the inclusion of women and minorities in clinical research.

At a minimum, NIH states that this document must address the following four points:

1. The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups for each proposed study or protocol using the format in the Targeted/ Planned Enrollment Table (which we will discuss in the next section of this chapter). If you are using existing specimens and/or data without access to information on the distribution of women and minorities, state so and explain the impact on your research's goals as part of the rationale that you cannot describe inclusion. Alternatively, describe the gender and minority composition of the population base from whom the specimens and/or data will be obtained.

2. The subject selection criteria and rationale for selecting sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design. Include, but do not limit yourself to, information

REMEMBER:

Cost is not an acceptable reason for excluding women or minorities except when the study would duplicate data from other sources.

> regarding the population characteristics of the disease or condition under study.
>
> 3. A compelling rationale for excluding any sex/gender or racial/ethnic group.
> 4. Proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

The following are examples of acceptable reasons to justify excluding human subjects based upon sex/gender:One gender is excluded because of the following:

- Including them would be inappropriate with respect to their health;
- The proposal's research question is relevant to only one gender;
- Evidence from prior research strongly demonstrates no difference between genders; or
- Sufficient data already exist regarding comparable studies' outcomes in the excluded gender, and duplication is not needed in this study.

The research's purpose constrains the applicant's selection of study subjects by gender (for example, a study of prostate cancer's survivor's ways of handling resulting sexual side effects would only include men).Gender representation cannot be accurately determined — for instance, studies of anonymous responses to a media educational campaign or datasets with incomplete gender documentation — and this does not compromise the research's scientific objectives.

For excluding minority groups or subgroups, the following examples show acceptable justifications:Some or all minority groups or subgroups are excluded from the proposed research because of one of the following:

- Including them would be inappropriate with respect to their health;
- The proposal's research question is relevant to only one racial or ethnic group;
- Prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;

- Your proposal involves a single minority group study to fill a research gap; or

- Sufficient data already exist regarding comparable study outcomes in the excluded racial or ethnic groups, and documentation is not needed in this study.

- The study's geographical location has only limited numbers of those minority groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:

- The study's size;

- The relevant characteristics of the disease, disorder or condition; or

- The feasibility of making a collaboration or consortium or other arrangements to include representation.

- The purpose of the research limits the applicant's study subject selection by race or ethnicity — for example, uniquely valued cohorts; very small numbers of subjects are involved; or overriding factors dictate subject selection, such as participants in available host agency sites.

- Racial or ethnic origin cannot be accurately determined — for instance, datasets with incomplete racial or ethnic documentation — and this does not compromise the research's scientific objectives.

If your proposal includes a Phase III clinical trial, this section also must address whether you expect clinically important sex/gender and/or race/ethnicity differences from the intervention effect. This discussion may include supporting evidence and/or data derived from animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology, and other relevant studies. Your discussion of expected sex/gender and/or race/ethnicity differences in intervention effect must include selecting and discussing one of the following:

- Plans to conduct valid analyses to detect significant differences in intervention effect among sex/gender and/or race/ethnic subgroups when prior studies strongly support these significant differences among subgroups; or

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups; or

- Plans to conduct valid analyses of the intervention effect in sex/gender and/ or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect among subgroups.

For example, this document could read as follows:

Our study focuses on the breast and cervical cancer screening behaviors of Asian immigrants from China, Vietnam, Cambodia and South Korea. As a comparison group, we are also including second generation, U.S. born women who are the descendents of immigrants from these same countries. Given the focus of the study, our sample will include only women. We are also excluding all other racial and ethnic groups other than Asians who either emigrated from the selected countries or are descendents of immigrants from the same countries because of our focus on cultural beliefs about screening. Our study will also exclude women below the age of 21 because we are looking for women who are of an age to make decisions for themselves.

Inclusion of Children

Direct from NIH:

4.4 Inclusion of Children

The NIH Policy on Inclusion of Children is referenced and described in Section 5.7 Instructions for Item 9 of the Research Plan are as follows:

- Create a section entitled "Inclusion of Children" and place it immediately following the Targeted/Planned Enrollment Table.

- For the purpose of implementing these guidelines, a child is defined as an individual under the age of 21 years (for additional information see http://grants.nih.gov/grants/funding/children/children.htm and http://grants.nih.gov/grants/guide/notice-files/not98-024.html).

- Provide either a description of the plans to include children, or, if children will be excluded from the proposed research, application, or proposal, present an acceptable justification for the exclusion (see below).

- If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan also must include a description of the expertise of the investigative team for working with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

- Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the age-appropriate inclusion or exclusion of children in the proposed research project.

- When children are involved in research, the Additional Protections for Children Involved as Subjects in Research (45 CFR Part 46 Subpart D) apply and must be addressed under the Protections Against Risk subheading (4.1.2.b).

What this means:

For this Human Subjects document, you should provide the following information regarding your proposed research's inclusion of children — which NIH defines as an individual younger than 21 years of age:

- A description of the plans to include children, or if children will be excluded from the proposed research, application or proposal, present an acceptable justification for excluding them.

- If children are included, the plan description should offer a rationale for selecting a specific age range. The plan also must describe the investigative team's expertise for working with children at the ages included, of the available facilities' appropriateness to accommodate the children, and the inclusion of sufficient children to contribute to a meaningful analysis relative to the study's purpose.
- SRGs assess each application as being acceptable or unacceptable based upon the age-appropriate inclusion or exclusion of children in the proposed research project.
- When you involve children in research, you must address additional protections placed for their safety in the Adequacy of Protection Against Risks section within the Protection of Human Subjects document.

At the same time, there are specific instances when NIH indicates you can justify excluding children — or a specific age range, such as younger than 18 years of age — from your research. Keep in mind, however, that NIH policy requires you to include children in all clinical research conducted or supported by the agency unless there are clear and compelling reasons not to include them. Here are examples of when you may exclude children from your proposal:

- The research topic is not relevant to children.
- Laws or regulations bar you from including children.
- The knowledge you seek is already available for children or will be obtained from another ongoing study, and an additional study will be needlessly redundant. In this case, you should provide documentation of other studies justifying the exclusions.
- A separate, age-specific study in children is warranted and preferable, including such examples as:
    a. The condition is relatively rare in children when compared to adults, meaning that you would need to make an extraordinary effort to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition; or

b. The number of children is limited because most are already involved in a nationwide pediatric disease research network; or

c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children — including different cognitive, developmental, or disease stages or different age-related metabolic processes. Although this situation may justify excluding children in some instances, NIH states that you should consider taking these differences into account in your study design and expand the hypotheses you are testing or the planned interventions to allow you to include children rather than exclude them.

- Insufficient data are available in adults to judge potential risk in children — in which case one of the research objectives could be obtaining sufficient adult data to make this judgment. Although you generally should not include children in the initial research study group, the illness' nature and seriousness may warrant their participation earlier based upon careful risk and benefit analysis.

- You concentrate your study designs to collect additional data on pre-enrolled adult study subjects such as longitudinal follow-up studies that did not include data on children.

- Other special cases that you can justify and the review group finds acceptable.

COMPLETE THE PLANNED ENROLLMENT REPORT

Direct from NIH:

The NIH is mandated by law (Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2) to ensure the inclusion of women and minority groups in clinical research. The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.

When submitting a new or competing renewal application/proposal to the NIH that includes NIH-defined clinical research studies, investigators should address plans for inclusion on the basis of sex/gender, race, and ethnicity as well as complete the Planned Enrollment Report. At a minimum, the inclusion plan should describe the proposed sample distributions by sex/gender, race, and ethnicity. You should justify the proposed sample in the context of the scientific goals of the proposed study. In addition to Planned Enrollment Reports, investigators submitting a competing renewal application should also complete a Cumulative Inclusion Enrollment Report(s) to describe progress on inclusion from the previous funding period.

When reporting these data in the aggregate, investigators should report: (a) the number of research participants in each ethnic category; (b) the number of research participants who selected only one category for each of the five racial categories; (c) the total number of research participants who selected multiple racial categories reported as the "number selecting more than one race," and (d) the number of research participants in each racial category who are Hispanic or Latino. Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information. However, more detailed data should be compiled in a way that they can be reported using the required categories.

Key changes in 2013:

- The Planned Enrollment Report will now include the "More than one race" category. The "More than one race" category will be used for reporting the planned number of individuals who you believe will identify with more than one racial category. Currently, this category has only been available when reporting actual cumulative enrollment.

- The layout of both the Planned Enrollment Report and the Cumulative Inclusion Enrollment Report has been modified to reduce confusion about racial and ethnic information being distinct concepts.

- The modified Planned Enrollment Report and Cumulative Inclusion Enrollment Report are structured data forms. As such, they will replace the need to attach enrollment tables as pdf files on electronically submitted competing grant applications.

What this means:

If your application is a renewal or revision and involves clinical research studies or social or behavioral science research, you must describe plans for enrollment, or reports on actual enrollment, of research subjects. This allows you to include summary data on participants and involves two categories of ethnicity and five racial categories — all based upon Office of Management and Budget (OMB) reporting standards for race and ethnicity data. As of late 2013, "more than one race" has been added as a racial category. All data are intended to be self-reported by research participants.

The Planned Enrollment Form is used to report your expected inclusion when you are preparing a new grant proposal and is included here:

Direct from NIH:

Planned Enrollment Report

This report format should NOT be used for collecting data from study participants.

Study Title:

Domestic/Foreign: Domestic

Comments:

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native					0
Asian					0
Native Hawaiian or Other Pacific Islander					0
Black or African American					0
White					0
More Than One Race					0
Total	0	0	0	0	0

PHS 398 / PHS 2590 (Rev. 08/12 Approved Through 8/31/2015)

Page ____

OMB No. 0925-0001/0002
Planned Enrollment Report

Field Name	Instructions
Study Title	Enter a unique title that describes the study that the participants will be involved in. If there is more than one study, provide a separate Study Title for each. Follow the instructions provided in the Application Guide and the FOA regarding the Inclusion of Women and Minorities. Maximum 250 characters. This is a required field.
Domestic/Foreign	Select whether the participants described in the planned enrollment report are domestic or foreign. At a minimum, domestic and foreign participants must be reported separately even if for the same study. This is a required field.
Comments	Enter information you wish to provide about this planned enrollment report. This includes but is not limited to addressing information about distinctive subpopulations if relevant to the scientific hypotheses being studied and/or a study that will have a delayed onset. Maximum 500 characters.
American Indian/Alaska Native	Enter the expected number of females and males (in the respective fields) who are American Indian/Alaska Native and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are American Indian/Alaska Native and Hispanic or Latino. These are required fields.
Asian	Enter the expected number of females and males (in the respective fields) who are Asian and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are Asian and Hispanic or Latino. These are required fields.
Native Hawaiian or Other Pacific Islander	Enter the expected number of females and males (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Hispanic or Latino. These are required fields.
Black or African American	Enter the expected number of females and males (in the respective fields) who are Black or African American and Not Hispanic or Latino, and; Enter the expected number of females and males (in the respective fields) who are Black or African American and Hispanic or Latino. These are required fields.
White	Enter the expected number of females and males (in the respective fields) who are White and Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who are White and Hispanic or Latino. These are required fields.
More than One Race	Enter the expected number of females and males (in the respective fields) who identify with more than one racial category and are Not Hispanic or Latino, and; enter the expected number of females and males (in the respective fields) who identify with more than one racial category and are Hispanic or Latino. These are required fields.
Total	The total fields at the bottom are auto-calculated to total all racial categories for females and males who are Not Hispanic or Latino and all racial categories for females and males who are Hispanic or Latino. The total fields at the right are auto-calculated to total all males and females of both Not Hispanic or Latino and Hispanic or Latino ethnicity in each racial category.

In addition, if your study is funded, NIH requires you to report the cumulative enrollment of subjects and their distribution by sex/gender and ethnicity/race using the Cumulative Inclusion Enrollment Report form (below) unless your program official indicates otherwise. If you are conducting more than one study, you should provide a separate table for each study. This is the form you will use when writing a renewal application, or when proposing to use data from an existing study in a new application.

Here is a version of the enrollment form filled out for the clinical trial of a culturally appropriate motivational interviewing protocol (next page):

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: A Randomized Clinical Trial of Culturally Tailored Motivational nterviewing

Total Enrollment: 250_____   Protocol Number: _____

Grant Number: _____

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
	Sex/Gender			
			Unknown or Not Reported	
Hispanic or Latino	125	125	0	250 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	125	125	0	250 *
Racial Categories				
American Indian/Alaska Native	1	1	0	2
Asian	1	0	0	1
Native Hawaiian or Other Pacific Islander	1	1	0	2
Black or African American	13	12	0	25
White	56	56	0	112
More Than One Race	0	0	0	
Unknown or Not Reported	54	54	0	108
Racial Categories: Total of All Subjects*	126	124	0	250

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories			**Unknown or Not Reported**	
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**				**

* These totals must agree.

** These totals must agree.

Direct from NIH:

Cumulative Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

Study Title:

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
American Indian/ Alaska Native										0
Asian										0
Native Hawaiian or Other Pacific Islander										0
Black or African American										0
White										0
More Than One Race										0
Unknown or Not Reported										0
Total	0	0	0	0	0	0	0	0	0	0

PHS 398 / PHS 2590 (Rev. 08/12 Approved Through 8/31/2015)

Page ____

OMB No. 0925-0001/0002
Cumulative Inclusion Enrollment Report

Field Name	Instructions
Study Title	Enter a unique title that describes the study that the participants will be involved in. The title should be the same as submitted on the original Planned Enrollment form for this study. Follow the instructions provided in the Application Guide and the FOA regarding the Inclusion of Women and Minorities. Maximum 250 characters. This is a required field.
Comments	Enter information you wish to provide about this Cumulative Inclusion Enrollment Report. This includes but is not limited to information if distinctive subpopulations are relevant to the scientific hypotheses being studied. Maximum 500 characters.
American Indian/ Alaska Native	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are American Indian/Alaska Native and of unknown/not reported ethnicity. These are required fields.
Asian	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Asian and of unknown/not reported ethnicity. These are required fields.
Native Hawaiian or Other Pacific Islander	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Native Hawaiian or Other Pacific Islander and of unknown/not reported ethnicity. These are required fields.
Black or African American	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are Black or African American and of unknown/not reported ethnicity. These are required fields.
White	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are White and of unknown/not reported ethnicity. These are required fields.
More than One Race	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and are Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who identify with more than one racial category and of unknown/not reported ethnicity. These are required fields.
Unknown or Not Reported	Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Not Hispanic or Latino, and; enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported and who are Hispanic or Latino; and enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are of unknown/not reported race and of unknown/not reported ethnicity. These are required fields.
Total	The total fields at the bottom are auto-calculated to total all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Not Hispanic or Latino; all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Hispanic or Latino, and all racial categories for females, males, and individuals of unknown/not reported sex/gender who are of unknown/not reported ethnicity. The total fields at the right are auto-calculated to total all individuals in a given racial category.

Note that NIH did not design these forms as data collection devices. Instead, the agency indicates that you should use for that purpose an instrument that you prepare for your study, and then use the information you collect to complete the form.

In addition, you should use the following OMB definitions when applying the ethnic and racial categories:

- Hispanic or Latino — a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."

- American Indian or Alaska Native — A person having origins in any of the original peoples of North, Central or South America and maintains tribal affiliation or community.

- Asian — A person having origins in any of the original peoples of the Far East, Southern Asia or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand and Vietnam.

- Black or African American — A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

- Native Hawaiian or Other Pacific Islander — A person having origins in any of the original peoples of Hawaii, Guam, Samoa or other Pacific Islands.

- White — A person having origins in any of the original peoples of Europe, North Africa or the Middle East.

- Ethnic/Racial subpopulations — In addition to the OMB ethnic and racial categories, NIH uses the following definition for ethnic/racial subpopulations:

  o Subpopulations — Each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins and/or cultural differences. It is recognized that there are

different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/ or cultural heritage. Attention to subpopulations also applies to individuals who self identify with more than one ethnicity or race. These ethnic/racial combinations may have biomedical, behavioral and/or social-cultural implications related to the scientific question under study.

The online forms you will use to complete your application will auto-total the various rows and columns.

OMB's data collection standards represent minimum requirements, and NIH encourages researchers to collect additional types of information that could provide insight into the relationships between race/ethnicity and health. For example, you might also choose to inquire further for those who choose multiple categories as to which they primarily identify. Or you might decide to ask participants if they consider themselves part of a subpopulation — for instance, if a subject indicates that he is Native American, you might ask him if he identifies as a member of a particular tribe or nation.

If you do decide to collect this additional information, you do not have to include it as part of your Planned Enrollment Form. But you should include it as part of your resubmission/renewal application.

For many more suggestions and FAQs on this topic, see the NIH page on inclusion at http://grants.nih.gov/grants/funding/women_min/women_min_qa.htm.

UPDATES TO THE NIH'S PLANNED AND CUMULATIVE INCLUSION ENROLLMENT FORMS

The following was released by the NIH on April 30, 2014 (Notice Number: NOT-OD-14-085):

On October 16, 2014, the NIH will transition to a new module within the eRA Commons (known as the Inclusion Management System, or IMS) used for reporting sex/gender, race, and ethnicity information as required by the NIH Policy on the Inclusion of Women and Minorities in Clinical Research (see NOT-OD-14-086). The previous system (known as the Population Tracking System) will be retired this summer.

The NIH is also transitioning to an updated format for reporting sex/gender, race, and ethnicity information. As noted in NOT-OD-13-092, the NIH has modified the format used to report sex/gender, race, and ethnicity information of individuals enrolled in clinical research studies. Applicants submitting competing applications have been using the updated formats starting with receipt dates on or after September 25, 2013.

It is now time to transition to the modified format for Type 5 non-competing progress report submissions using the PHS 2590 or the RPPR (Research Performance Progress Report) as we prepare to deploy the Inclusion Management System.

The notice goes on to say:

When submitting a progress report between July 18, 2014 and October 16, 2014 grantees will be directed to upload a PDF of the updated inclusion enrollment reporting format in section G.4.b of the RPPR rather than access a link to a structured data form.

Once the Inclusion Management System is available on October 17, 2014, grantees submitting non-competing Type 5 progress reports using the RPPR will have access to a link to the Inclusion Management System in Section G.4.b of the RPPR that will allow reporting of the inclusion enrollment data using the updated reporting format.

If using the PHS2590, use the PDF version of the updated inclusion enrollment reporting format.

Additional Resources: Additional guidance regarding these changes as well as other topics related to the inclusion of women and minorities in clinical research can be found at: http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Along this same line, Notice NOT-OD-15-005, was released on October 2, 2014. Titled 'Use of New Inclusion Management System Required as of October 17, 2014' it states:

The purpose of this NIH Guide Notice is to notify NIH applicants and grantees about using the new Inclusion Management System (IMS) for reporting sex/gender, race, and ethnicity information as required by the NIH Policy on the Inclusion of Women and Minorities in Clinical Research.   The existing system was retired for grantee use in non-competing progress reports in July 2014. The new Inclusion Management System will be released October 17, 2014, and will take advantage of the structured inclusion data being collected on competing applications to pre-populate inclusion data records and allow grantees to directly manage their inclusion data in the system throughout the awarded project period.

Key Changes for October 17, 2014, and beyond:

(1) Inclusion enrollment report forms received with competing application submissions will automatically populate the IMS.

(2) NIH grantees completing their RPPR (Research Progress Performance Report) will be prompted in Item G.4.b to access and update inclusion records directly in IMS.

(3) Grantees will be able to access their inclusion enrollment data through the IMS, found through the eRA Commons Status page, and can review or update their inclusion data as needed.

(4) NIH will migrate ongoing enrollment information from the previous data system to the IMS. Because the report format has been adjusted, grantees will be prompted to update Cumulative Inclusion Enrollment data in the IMS format at the time of the RPPR. They are encouraged to update Planned Enrollment data as well.

What this means:

The NIH is switching over to a new system for reporting, and now needs grantees to submit the required information, which hasn't changed, in a somewhat different manner.

INFORMING REVIEWERS ABOUT "SELECT AGENTS"

As in the case of using human or animal test subjects, you must create additional documentation — which you will upload as a separate document — if your research involves using "Select Agents." These are hazardous biological agents and toxins that the U.S. Department of Health and Human Services (HHS) and Department of Agriculture (USDA) identify as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. You can find a list of these agents, which the Centers for Disease Control and Prevention (CDC) maintains, at http://www.selectagents.gov/SelectAgentsandToxinsList.html.

A behavioral or social science research study will rarely involve select agents. The only times that you would need to pay attention to this form is 1) if your study was part of a biomedical study that involved select agents or 2) you are studying a population that may be infected with select agents. Examples include if you were studying the after effects of an Ebola outbreak and you came across materials that had been infected by Ebola or if you were studying intravenous drug users through an observation study and your staff could be at risk from accidental needle sticks that may carry AIDS. If your study includes any of these kinds of risks, follow the same directions as for a biomedical or clinical study.

Direct from NIH:

Select Agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC maintains a list of these agents.

If the activities proposed in the application involve only the use of a strain(s) of Select Agents which has been excluded from the list of select agents and toxins

as per 42 CFR 73.3, the Select Agent requirements do not apply. Use this section to identify the strain(s) of the Select Agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions at http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html.

If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to DHHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.

If any of the activities proposed in your application involve the use of Select Agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which Select Agent research will take place. Although no specific page limitation applies to this section, be succinct.

1. Identify the Select Agent(s) to be used in the proposed research.
2. Provide the registration status of all entities* where Select Agent(s) will be used.
   • If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where Select Agent research will be performed.
     * An "entity" is defined in 42 CFR 73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."
3. Provide a description of all facilities where the Select Agent(s) will be used.
   • Describe the procedures that will be used to monitor possession, use and transfer of the Select Agent(s).
   • Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).
   • Describe the biocontainment resources available at all performance sites.

If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the FOA.

Reviewers will assess the information provided in this Section, and any questions associated with Select Agent research will need to be addressed prior to award.

What this means:

If your research involves only using a strain(s) of Select Agents that has been excluded from the list, the Select Agent requirements do not apply. Nonetheless, you should use this document to identify the strain(s) of the Select Agent that you will use and note that it has been excluded from the list. You can find a list of these exclusions at:

http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html.

On the other hand, if the strain(s) is not currently excluded from the Select Agent list but you have applied or intend to apply to HHS for an exclusion from the list, use this document to indicate your request's status or your intent to apply for an exclusion and provide a brief justification for the exclusion.

If any of the activities proposed in your application involve using Select Agents at any time during the project period, regardless of where the research may take place, you must address the following three points for each research site where Select Agent research will take place:

1. Identify the Select Agent(s) you plan to use in your proposed research.
2. Provide the registration status of all entities — which NIH defines as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity" — where you will use Select Agent(s).

Even if the performance site(s) is a foreign institution, provide the name(s) of the country(ies) where Select Agent research will be performed.

3. Provide a description of all facilities where you plan to use the Select Agent(s).

   • The procedures that you plan to use to monitor possession, use and transfer the Select Agent(s).

   • Your plans for appropriate biosafety, biocontainment and security of the Select Agent(s).

   • The biocontainment resources available at all performance sites.

Here is an example of a select agent section from a successful grant application (Developing small molecule therapeutics for Ebola hemorrhagic fever virus, Principal Investigator: Amab Basu, PhD):

Select Agent

Select Agent to be used:

In vitro:

Ebola Zaire Mayinga Ebola Sudan Boniface Marburg Angola

In vivo:

Mouse Adapted Ebola Zaire Guinea Pig Adapted Ebola Zaire

Organization Name registration status:

Number and expiration date: XXXXXXXXX-XXXX expiration XX/X/XX

The foundation is a select agent registered entity with Health and Human Services, Centers for Disease Control and Prevention (CDC) and U.S. Department of Agriculture, Animal Plant Health Inspection Service, National Select Agent Program. The foundation has been inspected by the CDC National Select Agent Program for use of HHS Select Agents and Toxins, Overlap Select Agents and Toxins and USDA Select Agents and Toxins. Per the requirements of 42 CFR 73, is approved for use of select agents at BioSafety Level 2, 3, and 4 and Animal Biosafety Level 3 and 4.

Description of Facilities:

Procedures used to monitor possession, use and transfer of Select Agent(s)

The foundation maintains an experienced and trained staff of scientists, veterinarians, research technicians and veterinary technicians available to perform studies at high biocontainment and maximum containment. These individuals have demonstrated proficiency at conducting nonhuman primate studies with the agents identified in the proposal. The BSL3, ABSL3 and BSL4 Operations and Safety Manuals specify policies, procedures, and standard operating procedures (SOP) for the safe handling of biological materials in biosafety laboratories. The policies, procedures, and SOPs comply with application federal, state, and municipal regulations and with the guidelines "Biosafety in Microbiological and Biomedical Laboratories" issued by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). Employees are trained from these manuals on each facility's mechanical systems, biosafety, biocontainment and security. Employees are also trained according to project specific and departmental standard operating procedures.

These procedures apply to all foundation employees and visitors that use, generate, store, or dispose of potentially infectious materials in foundation biosafety laboratories and to persons who must enter those laboratories to

perform services. Prior to conducting experiments in the foundation biosafety laboratories, staff members must read and be trained in the requirements outlined in this manual and applicable task-specific safety plans.

At the present time, the director is the CDC designated Responsible Official (RO). Select agent use, transfer or possession is forbidden without the permission of the Responsible Official or Alternate Responsible Official, the required forms filed, and written approval received from the CDC Select Agent Program.

Upon approval, the BSK-3/4 Committee will consider select agents proposals for work in the BSL-3/4 laboratory. BSL-3/4-qualified investigators desiring to work on a BSL4 project must also submit a Biohazard Application to the Biohazards and Safety committee. The foundation Biosafety Committee has a key role in the foundation's overall biosafety program. The committee is responsible for evaluating the foundation's facility, equipment, and staff capabilities for performing work in a safe manner. The committee is also responsible for:

- Reviewing protocols and risk assessments submitted by principal investigators for work involving biological materials or toxins.
- Meeting with PIs prior to the implementation of projects involving biological materials or biological-derived toxins.
- Evaluating the foundation's staff, facility and equipment for their ability to provide the appropriate containment for handling biological materials.
- Assessing the foundation's compliance with existing federal, state and local environmental regulations.

Committee membership consists of representatives from technical departments, management, and administrative staff, among others. The committee communicates by e-mail with face-to-face meetings at least quarterly and/or more frequently if necessary.

Plans for appropriate biosafety, biocontainment, and security of the Select Agent(s)

Infectious cultures, inventory stocks or toxic materials are stored inside the BSL4 laboratory in refrigerators, incubators or freezers that are marked with the universal biohazard sign. Principal investigators maintain inventories of infectious agents stocks. A master list of select agents is securely kept by Virology and Immunology in the BSL4 Scientific Manager's office. A computerize and bar code inventory system has been selected for the select agent inventory. All issues relating to select agent inventory or tracking must be directed to the Responsible Official.

All infectious or toxic materials stored in refrigerators or freezers are properly labeled and stored in containers capable of withstanding thermal shock of freezing and thawing. Each container is labeled with the identity of the infectious agents, the date of the preparation, the initials or name of the responsible laboratorian and a reference number that links the material to the more inclusive information contained in the inventory database.

When work is completed, all infectious cultures and toxins are removed from workbenches and cabinets and stored in a designated refrigerator or freezer. Materials to be discarded are placed in a sealable container filled with a suitable disinfectant. The container is placed in a discard pan containing the disinfectant. Discard pans are placed in a cart and transported to the autoclave. Labware containing infectious liquids are stored and transported in leak-proof containers large enough to contain the fluid in case of leakage.

CONCLUSION

Finally, if you are using human or animal test subjects and/or select agents, NIH wants to know how and for what. Consequently, you will have to upload specific information as part of your grant application. But be sure you do not use these documents to bypass the Research Strategy page limits. ■

Chapter 7:
Budgeting Your Research

When applying for a National Institutes of Health (NIH) grant, in addition to your proposal's science, you also have to forecast how much money you will need to complete your research. Therefore, you should use the budget and associated justifications to present and support all the expenses required to achieve your proposal's objectives.

In fact, your budget's numbers are almost as important as — if not more so — the words you use to tell your research's story. This part of your application communicates to reviewers what you plan to do with the money you are asking them to invest in your project. Some reviewers even flip to the budget first to get a snapshot of the proposal and help them understand it. Although they should not take your budget into consideration as part of the assessment process, the information is available to them. And reviewers are told to evaluate the application and assign a priority score based upon the science and feasibility, and some believe the budget an indicator of feasibility.

REMEMBER:

Some reviewers flip to the budget first to get a snapshot of the proposal that will help them understand it.

There are two types of budget proposals that you can submit:

1. Modular budget
2. Detailed budget

You can use a modular budget for certain research grants if you request $250,000 or less per year for direct costs. These are simplified, so you would not submit detailed categorical information with these applications. You will input details about this type of budget on form PHS 398.

Detailed budgets — also called research and related (R&R) budgets — involve filling out three separate data entry screens as part of the R01 grant application.

And there are a total of 11 different sections that make up the three data screens. In addition, you have to complete a separate detailed budget for each year of support you request. So this can become a rather lengthy process.

Finally, your application's budget, regardless of the type you use, also includes several justification documents. These are narratives that you construct to indicate where you propose to spend your grant-related funds and why.

Budgets are normally developed by the PI in collaboration with their center or department and the university budget office. Depending on the size of the university, administrative staff with budget expertise at either your center or department, your school, or a university-wide budget office will work with you in developing the budget. The PI usually states the people and supplies they need for the project and the budget person finds the details and creates the formal budget. If you are an experienced PI, you will usually have a good sense of what to include in your budget and how long it will take to do the project. If you are a novice investigator on large projects, it is often helpful to seek the advice of a senior researcher at your institution about what needs to be included and how matching funds, in-kind contributions, etc. work at your university. In either case, you as the PI should be the one who has an overall sense of what personnel, supplies, travel, etc. you will need for your budget. You should not depend on the budget officer or administrative staff to create your budget for you.

That said, if your university or institution has any track record with government grants or funding from NIH, the budgeting staff that work with you to develop the budget should have a very good sense of university policies on budgets and what needs to be included. Listen to them and work with them collaboratively to create your budget. Unless you are at a school without these resources, budget staff will create the budget and format it using already established templates. You as PI are responsible for double checking that the budget includes everything you need. It is also helpful to have a second person check the math.

The PI is the only person who can create the budget justification, as it shows how you plan to do the research and use the supplies, equipment, etc. that is included in your budget. As with the substantive parts of your proposal, the budget and budget justification should be looked over by senior colleagues who have done similar research in your institution and an outside reader with similar expertise. They can tell you if you've missed anything or your budget looks right. They may also flag budget items that may raise questions in the review process.

Once you and your advisors in developing the proposal are satisfied with your budget, it usually needs to be reviewed by other administrative offices in the school or university. This process can take several weeks, and your budget staff should know the lead time needed to get your budget through the review process. Be sure to include enough time for budget review.

If you are developing a proposal with subcontracts or collaborators at other institutions, the staff at that institution will have to go through a similar budgeting and approval process for their portion of the budget. Be sure to check with your colleagues when you invite them to work with you on the proposed project to find out how long they will need to get budget figures for an initial budget and approvals from their university administration. You will need their information on salary and related costs BEFORE you develop your budget so that your university administrative staff can figure it into the total cost. Allow enough lead time to get this information. Also allow enough lead time for budget approvals at the institutions where each of your co-PIs and other participating colleagues work. If you are doing a consortium project, your other PIs may want to see your budget, so leave enough time for everyone to look it over.

Direct vs. Indirect Costs

For budgeting purposes, NIH makes a distinction between "direct" and "indirect" costs associated with your proposal:

- Direct costs — Those that can be specifically identified with a particular project or activity.
- Indirect costs — Also called facilities and administrative (F&A) costs, the grantee incurs these for common or joint objectives that cannot be identified specifically with a particular project or program.

When formulating a modular budget, you should consider only direct costs. For detailed budgets, however, you must include both direct and indirect costs. Keep in mind, however, that universities and other institutions commonly establish a single, negotiated contracted percentage rate to represent F&A costs for all NIH grants on their campuses, and you can obtain that information directly from your organization to include with your application's budget.

Note: From whatever award money you are granted, your administration will "take off the top," for itself, the F&A percentage it has negotiated with the government.

Also remember that if you have a subcontract or consortium agreement with another institution, you should treat any costs associated with that agreement as "direct," including that subcontracted organization's indirect costs.

STRATEGY FOR PLANNING YOUR BUDGET

The NIH application includes both R&R and modular budget components, and you can use these to continually revise and keep track of your budget's size during your application writing process. In fact, this can be a helpful tool in your budget planning process.

And the National Institute of Allergy and Infectious Diseases (NIAID) suggests that you should expect to spend time and effort crafting your thorough justification for your budget. "The more detail you include to justify it, the better — weak budget justifications are a big problem for many applications," the institute states.

If your budget expands beyond your grant type or career stage, you should consider cutting back your Specific Aims, number of sites or sample size, experts recommend.

Also, remember that NIH allows you to use grant money for certain specific costs, and it uses the following principles to define which costs you can charge to your grants:

- Allowable — Also known as "conformance," this principle centers on complying with the limitations and exclusions contained in the terms and conditions of the award, which can vary depending upon the type of activity, recipient and other characteristics of the specific grant.
- Allocable — You can allocate a cost to your grant if you incur it solely to advance work under the proposal, it benefits both the project and other work at your institution, or it is necessary to the overall organizational operation and is assignable to the grant at least partially.
- Reasonable — A cost may be reasonable if it and its associated costs reflect an action a prudent person would take under the circumstances prevailing when the decision to incur the cost was made.
- Consistency — You, as the Principal Investigator (PI), must consistently assign costs to cost objectives.

These four principles apply regardless of the type of budget you use.

Another key aspect to your budget strategy is knowing how much money to request. As the "Goldilocks" fairytale says, "Not too much, not too little, but just right." You should ask only for enough money to do the work you propose, but do not think that a "low ball," unrealistic budget will curry favor. In fact, you should keep the following in mind:

- NIH reviewers search grant applications for reasonable costs and judge proposals based on whether your Specific Aims and methods support your request.
- Reviewers also read the percent effort you list for each key person and judge whether they are in sync with their expectations based upon your application.
- If you significantly over- or underestimate your budget, reviewers often take this as you not understanding your work's scope.

Consequently, NIAID recommends that you should calculate salaries as 60 percent to 80 percent of your total budget request. When you formulate the PI's salary, remember the mandatory cap, which changes each year. You can find the salary cap information on NIH's Web site: http://grants.nih.gov/grants/policy/ salcap_summary.htm. And do not ask for anything that might appear extravagant, such as too much travel.

You should also use your budget to mention any discounts you receive. For example, if your university pays for the tuition for graduate assistants working on your project or your university gets a discount on supplies from Staples. You should note this in your budget documents because reviewers will want to know that you have established this relationship.

NIAID also recommends that you should not request funds for equipment or resources you have already listed as available in your Research and Other Related Project Information forms. If you do, reviewers will delete these items, and it may tarnish your credibility.

STRATEGY:

You should ask only for enough money to do the work you propose, but do not think that a "low ball," unrealistic budget will curry favor.

Alternatively, once you have determined the resources you will need for your project, identify what your institution can provide. Once you have this information, NIAID recommends that you ask the following:

- Does your institution offer you a budget for purchasing needed equipment?
- Will you have access to the necessary equipment, especially any large equipment (for instance, that costing more than $10,000) that you can share?
- If not, is there someone with whom you can collaborate who has access to that equipment?

At the same time, if you decide to request funds for equipment as part of your budget, NIAID offers the following guidelines:

- Requesting funds for small equipment or items not usually shared is fine.
- New investigators generally should avoid asking for expensive equipment. Study sections are more likely to approve such requests once you have firmly established yourself and are in charge of a larger group.

If you find yourself needing the expensive equipment as an absolute necessity for your proposal, however, make sure it is essential and justify it well, NIAID notes. You can create a separate module for that equipment, make it a one-time cost, and do not add it to your base amount.

TIP:

When deciding how much to ask for, experts recommend that you consider that each grant mechanism has a cap.

Also keep in mind any service contracts associated with such equipment. If NIH funds the equipment, such as specialized printers for maps or social network data, the agency will want to ensure it stays functional, and this includes grant funding for service contracts. Even if you share the equipment, you also share service contracts for this equipment, and you should reflect this in your budget.

When deciding how much to ask for, experts recommend that you consider that each grant mechanism has a cap. For example, R01s have a $250,000 yearly cap for modular budgets. And if you request $175,000 or $200,000 instead of $250,000,

as a new investigator, you can show reviewers that you are easing your way into the field, which could be a good thing, some experts note.

On the other hand, if you are performing human subject studies, you may need the full amount because such research is expensive. Therefore, be sure to explain in your budget request the expensive nature of your type of research. These expenses include the cost of researchers to collect and code data, both of which can be very time consuming. If you are doing any form of interviews, you should budget double the time you think it will take to actually do an interview to allow for multiple efforts to contact participants, schedule, and reschedule interviews.

Coding for either quantitative or qualitative software can also be very time consuming. While questionnaires can be in a machine readable format or entered directly onto the computer, someone still needs to check these data for errors. Budget time both for staff training and the actual coding/data checking work. If you are using a survey research firm or survey center within your university, they will be able to provide accurate estimates of data collection and coding costs.

If you are doing interviews that are taped or recorded through a computer, you will also need to budget for tape transcription. While rates vary across the country, usually it takes between 3 to 5 hours of transcription time for each hour of taped interview. Focus groups can take longer due to multiple voices. If you use voice recognition software, someone will still need to listen to the actual tape and correct the electronic system given frequent errors in these systems.

To ensure that you include everything you should in your financial plan, some experts recommend that you have someone else review it to search for anything that you have missed. You should also work closely with your sponsored programs office to ensure you complete your budget section correctly.

Not a Review Criterion, But …

Generally, NIH reviewers are not supposed to take your budget into consideration as part of the assessment process. They are there to evaluate the application and assign a priority score based upon the science and feasibility.

The budget, however, is there if reviewers wish to look at it — and many do — and factor it into their scores even though it does not appear on the official summary. After all, they say, the budget is one measure of a PI's experience and judgment.

If the reviewer considers your budget inadequate, you may be told that your proposal is "ambitious." Although excellent science is necessary to receive a good score, that is not sufficient. NIH is equally concerned with whether you will likely accomplish the goals and milestones you lay out in your application. Less experienced investigators often will try to show that they are a "bargain," thinking that the more "bang for its buck" the agency receives, the more impressed reviewers will be. This is not a good calculation because they usually do not care about a bargain. Instead, they care about you successfully completing the proposed study.

Moreover, less experienced investigators often think, "I'll say what I have to in the application to get the funding. I'll worry about actually carrying out the work after I have the money." On that note, be careful what you wish for.

The last thing you want is to win a grant award, and then spend as many as five years trying to fulfill your commitments with inadequate resources. In particular, one place where you can easily cut your budget is the amount of effort you allocate for you and/or your co-investigators. Keep in mind, however, that this will likely leave you overwhelmed because no matter what you list as your percent effort, you still have to do or oversee all the work or end with a poorly run grant.

So if your budget is too low, you make it difficult on yourself once you are funded. And you run the risk of failing to honor your commitments to NIH, which may cost you in the long run.

Note: Many comments in this section courtesy of William Gerin, PhD, Professor of Biobehavioral Health at Pennsylvania State University.

REMEMBER:

If the reviewer considers your budget inadequate, you may be told that your proposal is "ambitious."

CREATE YOUR BUDGET

When you create your budget, remember that reviewers often use it to judge your competence by comparing it to your project's scope.

If you are from a domestic institution and request $250,000 per year or less in direct costs for your proposed project, you can use a modular budget. This is a simplified method for requesting funds, meaning you do not need to submit detailed categorical information with your application.

Using modular budgets, PIs request funding in $25,000 increments. Keep in mind, however, that this funding mechanism offers no inflationary increases for future years, which requires you to plan your entire budget at the outset.

On the other hand, if you are applying for a grant from a foreign institution or for more than $250,000, you will need to submit an R&R budget. This will require the following:

- Using the R&R budget component forms (Application Sections A-K).
- Requesting a salary below the annual cap.
- Ensuring your direct institutional costs are consistent on all budget forms.
- Using whole numbers for person months and percent effort, and dollars for costs. Rounding calculations to the nearest dollar, but institutional costs do not need to be in whole numbers.

REMEMBER:

Modular budgets offer no inflationary increases for future years, which requires you to plan your entire budget at the outset.

Modular or Detailed Budget?

To determine whether you should choose a modular or R&R budget, use the following flow chart from NIH:
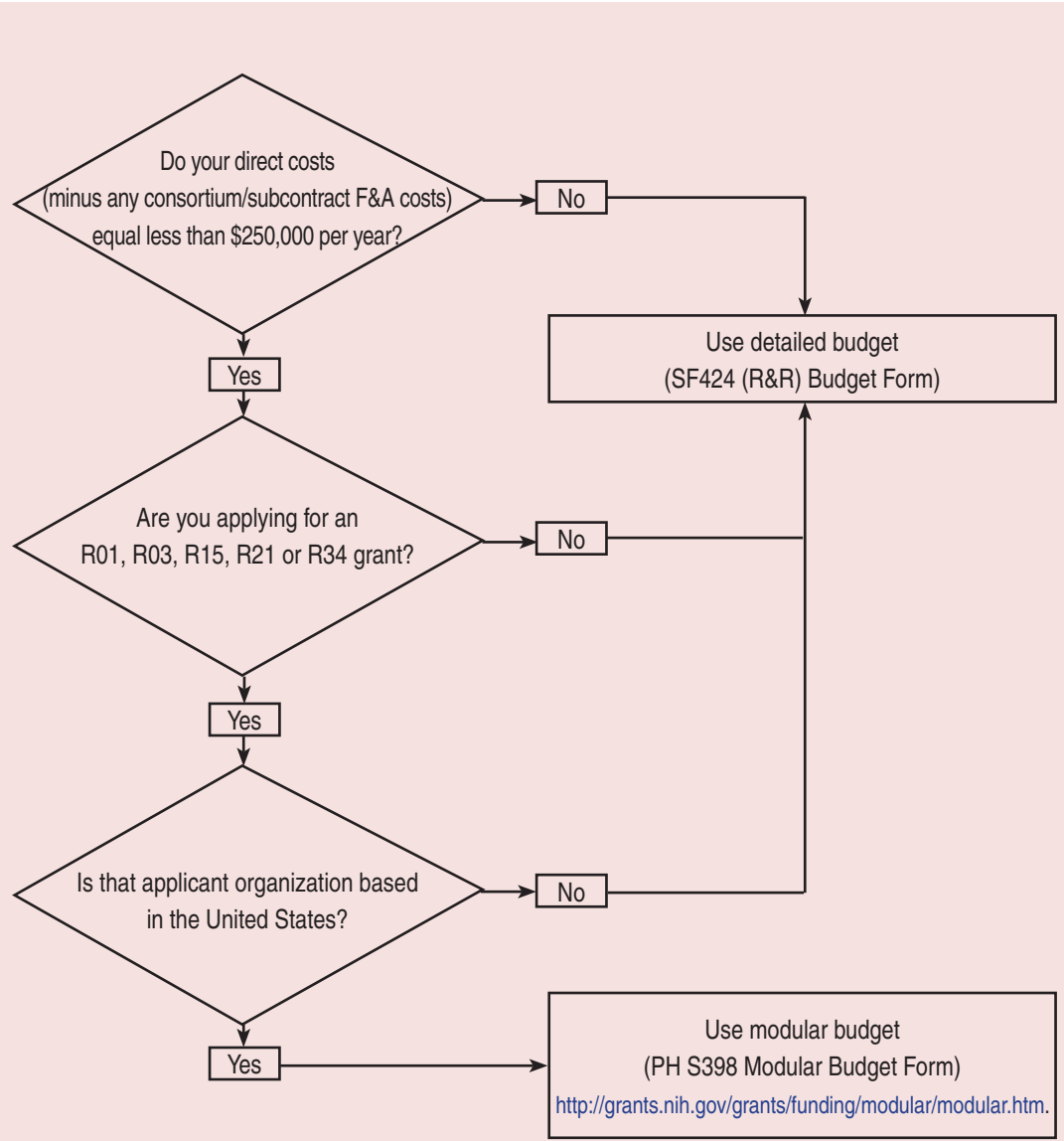
Source: National Institutes of Health

Modular Budgets Have a Limit

Direct from NIH:

Modular budgets are applicable to certain research grant applications from domestic organizations requesting $250,000 or less per year for direct costs. International organizations and others that do not fall under this definition should use the detailed budget forms described in Section 4.7. Note, consortium/contractual F&A costs are not factored into the direct cost limit. They may be requested in addition to the $250,000 limit. Modular budgets are simplified; therefore, detailed categorical information is not to be submitted with the application.

For all modular budgets, request total direct costs (in modules of $25,000), reflecting appropriate support for the project. There will be no future year escalations. A typical modular grant application will request the same number of modules in each year. Provide an additional narrative budget justification for any variation in the number of modules requested.

What this means:

Once you have determined your budgetary needs in $25,000 increments — not to exceed $250,000 — you must support your monetary request. For modular budgets, you will do this by completing three narrative "justifications":

1. Personnel Justification
2. Consortium Justification
3. Additional Justification

Some applicants might be tempted to add details of their scientific approach to the budget justifications sections to boost their chances of getting all the

funding they seek. Although reviewers do carefully consider these financial planning documents, they generally are only making sure the budget is appropriate for the proposed research. Your goal is to link your budget to your scientific approach and methods, but not think of the budget as additional space to explain your methods or the rationale for your research.

Therefore, details about your methods are inappropriate for this section because you cannot be sure your reviewers will read it. If your approach requires something that is unusually expensive, such as lots of money for tape transcription or participant observation, however, then definitely do point that out in the budget section.

Note that your budget request should not factor in your overall impact score because it is in the "other" category, which is discussed after a score is assigned. On the other hand, if reviewers think your request is excessive, they will recommend cuts. And there may be "budget envy" among some reviewers, especially if your salary structure looks high — as at a private company or national lab. Be sure to explain your salary structure in the Personnel Justification if you think that might be an issue.

Personnel Justification

Direct from NIH:

List all personnel, including names, percent of effort and roles on the project. NIH and other PHS agencies use the concept of person months as a metric for determining percent of effort. To assist applicants unfamiliar with this concept, resources are available on the web at http://grants.nih.gov/grants/policy/person_months_faqs.htm. Frequently asked questions and a conversion calculator are available.

No individual salary information should be provided. Since the modules should be a reasonable estimate of costs allowable, allocable, and appropriate for the proposed project, applicants must use the current legislatively imposed salary limitation when estimating the number of modules. For guidance on current salary limitations contact your office of sponsored programs.

NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. This limit should also be used when estimating the number of modules. See: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html.

What this means:

For the Personnel Justification, you should list all personnel working on the project, their roles and the number of person months they will devote to the project. A "person month," according to NIH, is the measure you should use to indicate the amount of time PIs, faculty and other senior personnel devote to your project.

To calculate person months, multiply the percentage of your effort associated with the project by the number of months of your appointment. NIH offers the following examples:

- 25% of a 9-month academic year appointment equals 2.25 person months (9 x 0.25 = 2.25)
- 10% of a 12-month calendar year equals 1.2 person months (12 x 0.10 = 1.2)
- 35% of a 3-month summer term appointment equals 1.05 person months (3 x 0.35 = 1.05)

In addition, your personnel justification should briefly describe each person's responsibilities in enough detail to justify the person's level of effort. But you

should not include salary information in this document. And you should include all key personnel even if you know they will be gone when the application is funded, NIH says.

Budgeting Effort Can Be Delicate Task

When budgeting effort for the PI and/or co-investigators, you should start with a pragmatic analysis. How much time will the particular investigator need to allocate to accomplish their project-related duties? Think in these terms: There are 40 hours in a standard work week, and 20 percent effort would mean that person in theory would work on the project one full eight-hour day each week.

And there are additional considerations. For example, you plan to list a senior colleague as a co-investigator. You actually do not expect him to do much, but his well-known name will be useful perhaps as a political expedient, and you might feel awkward if you left him out. Consequently, you might list him at 5 or 10 percent effort. Also keep in mind that even at such a limited level, including such a senior-level salary on your budget could add approximately $25,000 or more.

As for co-investigators who will do the work outlined in your proposal, you have to find the balance between what they have to do, how much you can afford and what would appear questionable to a reviewer. For instance, if you budget a co-investigator in charge of data collection at only 3 percent of her salary, the reviewer likely would find this unreasonable. Or if a co-investigator's main job is to help with data analysis that does not begin until Year 4, the reviewer likely would be concerned if you budget them at 20 percent effort for all five years of the grant.

To avoid this, you should determine effort allotments based upon the following criteria:

1. Actual effort as matched to the anticipated work level
2. "Political" and personal considerations

STRATEGY:

As for co-investigators who will do the work outlined in your proposal, you have to find the balance between what they have to do, how much you can afford and what would appear questionable to a reviewer.

3. Funds that are available

4. Appropriateness of the effort level as perceived by reviewers.

When considering effort for consultants, you will use the budget justification section to describe not only what she will do, but also how many days per year she will spend on the project and at what fee per day. You can break the cost down by days or number of hours.

The consultant's fee will vary depending on specialty, seniority and the credentials she has. A lower-level consultant, for example, might be someone from another university with fluency in a language spoken by part of the population you plan to include in your research. You might budget this person at $30 per hour, or roughly $250 per day. A more senior consultant might require $500-$1,000 per day, depending on seniority and fame. Keep in mind that if you pay one consultant too much per day, you run the risk of a reviewer flagging your application negatively.

Another type of staff expense is staff at the sites that are hosting your research who will be involved in the project. For example, if you are doing a project at a hospital or clinic, you may buy part of the time of an outreach staff person to help you recruit participants for your study. If you are working with a clinician at your host site as a co-PI, a portion of their salary would be included in the grant using the same rules for caps and maintenance of effort as for someone from a university. If you were hiring parks and recreations staff to fill out observations, you would need to either pay for a portion of their salary or pay them per interview or form filled out. These costs would all need to be explained in your budget justification.

Working with community based organizations can also yield a different set of costs. You may want to rent space from participating organizations or provide a donation to thank them for their participation. Say for example that you were hiring interviewers for a study of people with disabilities from organizations serving people with disabilities throughout the state. The interviewers would be paid on a regular hourly or per-interview rate as part-time staff or consultants at your institu-

tion. However, to facilitate their work, your project plans to borrow office space from the host agencies and rely on job coaches to ensure that interviewers with disabilities have the accommodations, transportation, etc. to do their work. This may be a significant expense for the agency, even though you are helping them fulfill their mission of finding jobs for their participants. A modest donation of $250 to $500 may make a significant difference in the budget of these agencies and create the good will needed to successfully carry out your project.

In another example, you might train youth from a neighborhood high school to collect data through observations or interviews. This would be part of their education or count toward mandatory community service, so they would not be paid. However, your budget might include incentives like pizza, supplies, and back packs or tee shirts to thank them for their work.

Social and behavioral science projects also often include incentives for people to participate in the project. For example, someone who responds to a one time questionnaire may get a thank you gift of a $10 gift certificate. People participating in a longitudinal study may get a small incentive, like a $5 gift certificate or a pen, for each interview and a final payment of $50 upon completion of the interview. Standards for incentives vary by region and type of research. Colleagues who have conducted similar projects and your university administration should have some sense of the usual incentives and their costs. Sometimes research projects can get incentives like gift cards or small goods like mugs, pens, or water bottles with the project logo at a discounted rate.

In some cases, large chain stores that support research on your topic may donate low dollar gift cards for participant incentives as an in-kind donation to your project. These kinds of matches can be as important as funding from other sources or in-kind matches from your university in showing that others want to contribute to your project. In-kind matches should be explained in your budget justification.

Each of these categories of expenses will depend on the methods you choose and the personnel you have available to carry out your project.

Follow This Example

The following is an example of a Budget Justification taken from a successful R01 grant application.

From NIDA sponsored project 1R01DA034072-01A1 SUBSTANCE USE IN RESERVISTS SOCIAL AND ENVIRONMENTAL INFLUENCES

Personnel

PI, Ph.D., will serve as Principal Investigator. Drs. A, B and C will serve as co-investigators. The investigators are responsible for the scientific integrity of the research. They will oversee all aspects of the study including: the selection of measures and development of the research protocol, the hiring and training of research staff, and ongoing supervision of data collection. Once data are collected, they will analyze the data, develop presentations for scientific conferences and prepare and submit scientific papers for publication.

Dr. PI, Pl, is an Assistant Professor of Community Health and Health Behavior in the School of Public Health and Health Professions, a Research Assistant Professor in the Department of Family Medicine and an Associate Research Scientist at the Research Institute on Addictions, all part of the University B, and holds a 12 month appointment. He will devote {redacted- % effort} **calendar months** effort to each year of the project. He will lead the project and be responsible for oversight of all fiscal and administrative management and all communication with NIH and the University. He will also be responsible for submitting progress reports to the NIH.

Dr. A ,Co-I, is the Dean of the School of Public Health and Health Professions and a professor of Community Health and Health Behavior at the University B, . He holds a 12-month appointment at the University. He will devote {redacted- % effort} calendar months effort in years 1 and 5 of the project. Dr. A's efforts on the

current project will be centered on tobacco use (cigarette smoking as well as other tobacco use). **Given the new theoretical model (social-ecological model) for the application, it is important to note that such biopsychosocial approaches have been central to Dr. A's approach to research and that he has regularly taught sections in graduate courses focusing on the use of ecological models in health research.** [Note: NIH Salary Cap]

Dr. B, Co-I, is the Director of the Research Institute on Addictions at the University B,. He holds a 12-month appointment. Dr. B will devote {redacted - % effort} **calendar months** effort in all years of the project. Dr. B's effort on the current project will be focus on intimate partner aggression (physical, verbal, and sexual), alcohol use, and longitudinal methodology. {Redacted- review comments/ responses}

Dr. C, Co-I, is an Associate Research Professor in the Department of Social and Preventive Medicine at the University B,. He holds a 12-month appointment and will devote {redacted- % effort} **calendar months** in all years of the project. Dr. C will focus his effort on military issues, stress, and issues related to PTSD symptomatology. {Redacted- review comments/responses}

To Be Named, Project Director - Funds are requested for a project director for 12.00 calendar months effort in each year of the study. This person will be responsible for the day-to-day operations of the research project and supervision of the research staff. Specific tasks include training and supervising the research staff, developing and maintaining procedural manuals, overseeing subject scheduling and data collection and data entry.

To Be Named, Research Technician II (RT) - Funds are requested for three research technicians; one RT at 9.00 calendar months effort and two at 6.00 calendar months effort for all years of the grant. The RTs will initially assist with testing the program of the ACASI system. They will be responsible for scheduling and conducting all assessments with husbands and wives, following up on missed appointments, ensuring subject payments are processed, collating data that will

be entered manually and will assist with manuscript preparation (e.g., literature searches, etc.).

D, MS, Graduate Research Assistant - Funds are requested for {redacted- % effort} calendar months of effort for all years of the project for a graduate research assistant. D is a PhD candidate in the Department of Community Health and Health Behavior under the mentorship of [Redacted]. They will be involved in several aspects of the project including research interviewing, consenting process, as well as data management and analysis.

Annual cost of living increases are applied to budget categories according to UB guidelines.

Fringe benefit rates and indirect cost rates are based on the applicable federally negotiated rates published at http://www.research. B.edu/sps/about/rates.cfm

Other Significant Contributors

COI (retired) F   will serve as a consultant on the project for {Redacted- % effort} days in years 1 through 5, at a cost per of {Redacted – base salary} per day. COL F   is a Senior Research Fellow, Center for Technology and National Security Policy, National Defense University. His research interests include military psychology, stress, adaptation, and resilience on not only the service member, but also his/her family. He will consult on issues related to stress (PTSD symptomatology) as well as issues related to reservists and their families.

Dr. G will serve as a consultant {Redacted- % effort} days each year at {Redacted- base salary} per day. Dr. G was added to the grant in response to reviewers' comments regarding staffing of the grant as it relates to scientific productivity. Dr. G is a professor of psychiatry at the University of D and has been a faculty member at the Veterans Administration (VA) Healthcare System for the last ten years, and has served as the Director of the VA Comorbidity Clinic during that time as a faculty member of the VA MIRECC

Comorbidity center grant. Dr. G will consult on issues related to treatment and prevention of substance use disorders. It is important to note the Pl and Dr. G have collaborated on a variety of grants and papers dealing with substance use disorders, resulting in 8 papers published in major journals and 13 national presentations.

Dr. J will serve as a consultant on the project for {Redacted- % effort} days in years 1, 2 and 5 at a cost of {Redacted- base salary} per day. Dr. J is a Professor in the Department of Psychology, X University and Acting Executive Director of Veterans Integrated Service Network (VISN) 2's Center for Integrated Healthcare. His efforts will focus on substance use and military issues.

Travel

Funds are requested for in the amount of $2500 to facilitate face-to-face consultation and collaboration in year 1 with the Pl and consultants on this project. In year 1, funds are also requested, at a cost of $2500, to facilitate the project director's attendance for CIDI Training.

Attendance at annual conferences sponsored by organizations such as the College on Problems of Drug Dependence and American Public Health Association provides the opportunity to exchange ideas with others conducting related research and also to present findings. Therefore, $2,500 is requested for Years 2 through 5 for Dr. PI and/or co-investigators to attend one scientific meeting.

Supplies

In Year 1 two computers, at a cost of $1,500 each, to be utilized for project management and data analysis are requested. Funds are also requested for six tablet computers, at a cost of $2000 each (3 are needed for the RT staff, and three additional tablets are requested for conducting multiple interviews simultaneously). These tablet PCs will be used for both interviewing and for the RT's daily work;

therefore desktop computers have not been included in the budget for RTs. Because of the use of the tablets for interviewing in multiple locations, carry cases are requested for a cost of $150 each. In addition, two desk printers, at $150 each are requested for project related printing and mailing preparations.

Funds for project supplies (two digital recorders at a cost of $400), which are needed to create the audio version of the questionnaires that are administered to the participants; additional supplies include: reminder postcards, headphone booties for audio interviews, headphones, project stationery, etc.) in the amount of $2130 in year 1.

Software and Software Maintenance

STX: STX is the company that will provide our secure HIPAA compliant database that will maintain all participants' records, enable appointment scheduling and reminder services, capture all data from the IVR computer systems, capture all data from baseline and follow-up assessments, and provide technical support for the deployment of the ACASI interview (See letter of support). Costs tor this service are {redacted- proprietary} in year 1 and {redacted- proprietary} for a multiyear contract (for years 2-5). The multiyear contract allows for continued programming support, service, maintenance, and software upgrades.

<u>Other Expenses</u>

<u>Subject Fees</u>

Funds to compensate the subjects are requested for their participation in the study and would be paid at scheduled assessments. The yearly detailed breakdown of these costs is provided below.

Year 1:

Assessment Time	Amount Per Assessment	Number of Assessments	Total
Baseline Interview	{Redacted- Proprietary}		
Follow-up Interview 1			
Follow-up Interview 2			

Total Subjects Fees Year 1 $8100

Year 2:

Assessment Time	Amount Per Assessment	Number of Assessments	Total
Baseline Interview	{Redacted- Proprietary}		
Follow-up Interview 1			
Follow-up Interview 2			

Total Subjects Fees Year 2 $33750

Year 3:

Assessment Time	Amount Per Assessment	Number of Assessments	Total
Baseline Interview	{Redacted- Proprietary}		
Follow-up Interview 1			
Follow-up Interview 2			

Total Subjects Fees Year 3 $54000

Year 4:

Assessment Time	Amount Per Assessment	Number of Assessments	Total
Baseline Interview	{Redacted- Proprietary}		
Follow-up Interview 1			
Follow-up Interview 2			

Total Subjects Fees Year 4 $47250

Year 5:

Assessment Time	Amount Per Assessment	Number of Assessments	Total
Baseline Interview	{Redacted- Proprietary}		
Follow-up Interview 1			
Follow-up Interview 2			

Total Subjects Fees Year 5 $18900

Retention Incentives

Funds are requested to provide incentives for participants to remain actively involved in the study throughout the three waves of data collection. Each participant will receive an incentive valued, at $5.00 (including postage), on two separate occasions, once halfway between the first and second in-person interview (810 participants *$5=4050) and once halfway between the second and third in-person interviews (810 participants *$5=4050). To ensure adequate supply is on hand, and to obtain bulk discounts, all incentives will be purchased in year 1.

Printing

Funds are requested in the amount of project printing costs for screening questionnaires, manuals, and related documents. ($500 year 1; $1000 in year 2).

Tuition

We are requesting funds in the amount of $8820 in each year for the graduate student tuition. Tuition in the School of Public Health and Health Professions is $490 per credit hour; we are budgeting for 9 credit hours per semester.

One element of this budget deserves particular note. In personnel, the project requests funds for a full time project director. This person may be a co-PI, research professor or recent PhD with administrative experience who is responsible for the day–to-day operations management of the project, as well as some of the research. Any large project should have a full time project director or project manager to make sure all of the pieces run smoothly. Both project officers and reviewers look for someone on the project who has a 50% to 100% time commitment who will be responsible for project operations. Without someone who can manage the operational details of the project on a daily basis, a project like this is not likely to succeed.

.

Consortium Justification

Direct from NIH:

Provide an estimate of total costs (direct plus Facilities and Administrative) for each year, rounded to the nearest $1,000. List the individuals/ organizations with whom consortium or contractual arrangements have been made. List all personnel, including percent of effort, using the metric of person months, and roles on the project. No individual salary information should be provided. Indicate whether the collaborating institution is foreign or domestic. While only the direct cost for a consortium/contractual arrangement is factored into eligibility for using the modular budget format, the total consortium/contractual costs must be included in the overall requested modular direct cost amount.

What this means:

Consortiums are agreements between the applicant and a collaborator, which can be an individual or an organization, to carry out a portion of the grant-supported research. If you receive an NIH grant, you will be directly and primarily responsible for the funds, as well as accountable to the agency for performing the project.

In the Consortium Justification, you must provide details of any consortium agreements. This includes total costs associated with each such agreement rounded to the nearest $1,000. You should also outline any personnel considerations, including the roles and person months, and whether the consortium involves a foreign individual or organization.

Follow This Example

The following is an example of a Consortium Justification taken from a successful R01 grant application from NIA sponsored project 1R01AG041955-01A1 Understanding How Personal Networks Change

BUDGET JUSTIFICATION

Personnel:

Key Personnel

- **Professor PI** will serve as **Principal Investigator,** {Redacted- % effort} **Months.** The PI will be responsible for supervising the research as described in the proposal.

  His duties will include supervision of professional and technical staff and of the postdoctoral fellow and graduate student researcher(s); collaboration with other investigators to manage the data collection process, test the study hypotheses and assure timely and thorough analysis and interpretation of data; integration and synthesis of study findings and preparation of interim and final reports. Dr. PI will also actively seek to disseminate the study findings at scientific meetings and will prepare scientific manuscripts for peer-reviewed journals or monographs.

  Dr. PI is a nationally and internationally recognized expert on personal and social networks and using the name-eliciting methodology which he developed, and has published several books and articles on this subject.

Other Significant Contributors

- **Dr. A** will serve as a **consultant for sampling statistics** {Redacted- % effort} Months. He will design and monitor sampling strategies, and assist in developing sample weights. He has served in this capacity previously for the U Survey Research Center and currently teaches the survey sampling class in the School of Public Health.

- **Professor B** {Redacted- % effort} Months, Year 1 through 4, will serve as a **consultant** for design and implementation of the panel studies. He has worked in this area and published extensively on panel studies and will be a critical contributor to this research.

- **TBD, Professional Researcher.** (1.0 Summer Month, Years 4 and 5.) This person will most likely be an assistant or associate professor at U who will be mentored into taking over this research project and taking it into its next phase. In the final year of this project, the researcher will collaborate with the Pl and project scientist on presentations and publications, and seek the next stage of funding.

- **TBD, Specialist (Project Scientist), (6.0 Calendar Months).** The Project Scientist will be responsible for day-to-day management of project, including coordination with vendors, supervision of staff, data storage. This person will also contribute to analyses and writing of papers, presentations and reports, and preside over presentations at national conferences regarding the data set.

Other Personnel

- **TBD, Graduate Student Researcher, (4.5 Academic Months AY each year, and 2 summer months in year 5).** The Graduate Student Researcher will be responsible for general assistance in refining methodology, cross-checking data, validation runs, eventually assisting research report writing.

- **TBD, Software Analyst**, (6.0 Academic Months.) The Software Analyst will be responsible for researching, developing, and setting up statistical

systems for panel causal analysis; incorporating weights, conducting analyses and developing documentation.

- **TBD, Post-Doctoral Researcher, (12.0 Calendar Months, Years 4 and 5).** The Post doctoral researcher will be responsible for data-analysis, report-writing in collaboration with Pl.
  - Salary is increased at a rate of 2% per year for the Principal Investigator, the Graduate Student, the Post-doctoral, Researcher and the Project Scientist and 3.5 for the Software analyst to allow for cost of living adjustment.

Fringe Benefits:

- Fringe benefits for **Prof. PI** are calculated at the University of C rate of 33.35% of salary.
- Fringe benefits for the **Graduate Student Researcher** are calculated at the University of C of 1.78% of their salary.
- Fringe benefits for the **Software Analyst** are calculated at the University of C rate of 40.22% of monthly salary.
- Fringe benefits for the **Post-Doctoral Researcher** are calculated at the University of C rate of 18.85% of their calendar year salary.
- Fringe benefits for the **Specialist (Project Scientist)** are calculated at the University of C rate of 19.28% of monthly salary.
- Fringe benefits for the **Professional Researcher** are calculated at the University of C rate of 33.25% of salary.

The University of C provides full remission of tuition, fees, and graduate student health insurance to all graduate students who are employed on-campus 45% time or greater during the academic year. The rate for in-state remission is $ 9,065 per semester, which is escalated annually in the budget at a rate of 10% per year.

Other Expenses:

Consultant:

Professor N, G University, who will provide expertise around the survey instrument design to include appropriate health measures, and input regarding interpretation of results.

Data Collection:

Research Firm B: They will acquire the DSF file from a certified vendor, M, send out the initial mailing and handle all recruitment issues. Follow-ups on the telephone will be made using the matched phone sample to increase participation. They will work with RESEARCH COMPANY C to ensure a streamlined process for communicating about panel members, and integrating the RESEARCH COMPANY C web-based software and CAPI systems for web-based and face-to-face surveying. Research Firm B will also schedule interviews, conduct face-to-face interviews, manage the panel of respondents to keep them in touch in-between waves, and handle fulfillment of the incentives.

RESEARCH COMPANY C: RESEARCH COMPANY C will contribute in the following manner:

1. Program and test the survey
2. Set up Sample Management System and data transfer system from 4 offline netbooks and web respondent panel management.
3. Prepare Administrative data site for researchers to download data.
4. Support for sample management (based on sample delivered from Research Firm B for web-based surveys; plus keeping track of response and non-responders),database management (integration of web and CAPI)
5. Follow-up survey programming for the web-based survey and CAPI, including preload and data manipulation to clean preload variables.
6. Provide secure servers for hosting the survey.
7. Calculate sample weights.

Domestic Travel.

Funds are requested for 5,510.00 for travel (a) incidental to survey development (e.g., to interviewer training sessions - $200 each year; (b) conferences (American Sociological Association, Gerontological Society of America and/or Population Association of America) for delivering reports (calculated at: $80 parking, $240 food, $200 registration; $250 each night for 3 nights lodging, and $500 airfare) for the key personnel and significant contributors)

Materials and Supplies:

Funds are requested for 960.00 for software licenses to be used by the Pl, post-doctoral scholar and graduate student researchers. There will be two survey vendors. The first is RESEARCH COMPANY C who will provide us services for web-based data collection, using their proprietary software. They will also assist the second vendor, Research Firm B in San Francisco with integrating the web and CAPI (computer-assisted personal interviewing) software to be utilized in the face-to-face interviews. The costs for Research Firm B are $1,180,508.00 to cover recruiting of the initial sample, panel management and 3 waves of face-to-face survey data collection. The fee to RESEARCH COMPANY C will be $69,775 to cover web programming, data collection and data set preparation, and integration of software and files with Research Firm B.

Indirect Charges:

Indirect cost charges are calculated using Modified Total Direct Costs (Total Direct Costs minus equipment, graduate student's tuition remission and health insurance, and subaward costs in excess of $25,000 per subaward). U's new federally negotiated IDC rates for on-campus organized research are: FY 2013 = 55.5%; FY 2014 = 56.5%; FY 2015 = 56.5%; FY 2016 = 57.0%.''

Additional Narrative Justification

Direct from NIH:

If the requested budget requires any additional justification; e.g., variations in the number of modules requested, save the information in a single file and click the add attachment button to complete this entry.

What this means:

In most cases, applicants request the same number of modules each year, except for special needs like equipment. If the number of modules you request vary from year to year, this section is where you will explain why.

One additional expense increasingly included in social and behavioral science proposals is funding for an evaluation of the research project itself. This can include an internal evaluation such as software that will track the number of interviews conducted in a given period, completion rates and so forth. In this case, no additional salary would be included for the evaluation, but the costs for project management software might be included.

Increasingly, reviewers look for outside evaluators on a large research project. Evaluators may be a consultant who attends project meetings and evaluates the interim results of your project. They may produce several reports throughout the project. For a clinical trial, the evaluator may be a separate component of the project that conducts in independent evaluation of how successful the processes of the research are in achieving the clinical trial or intervention test's goals. In each case, fees for the consultant or evaluation firm should be included in the budget. In many cases, the evaluator would be part of the regular budget and budget justification. In large modular budgets, costs affiliated with the evaluation may be entered as an additional budget justification attachment.

TIP:

In most cases, applicants request the same number of modules each year, except for special needs like equipment.

NIH REVIEW PROCESS: A BRIEF OVERVIEW

Direct from NIH:

If funds are being requested for more than one budget period, you must complete a separate detailed budget for each year of support requested. To navigate to screens for the next budget period, click the Next Period button at the top of the 3rd budget screen (Sections F through K). You must complete all the required information (i.e., those fields that are highlighted and outlined in red) and/or confirm/update any pre-populated information before the Next Period button is activated. If no funds are requested for a required field, enter "0." Note the Budget Justification is also a required item and must be attached before the Next Period button is activated.

What this means:

If you are submitting a detailed budget, there are 11 separate sections (designated A-K) that you will have to complete. These break down as follows:

- A: Senior/Key Person
- B: Other Personnel
- C: Equipment Description
- D: Travel
- E: Participant/Trainee Support Costs
- F: Other Direct Costs
- G: Total Direct Costs (A through F)
- H: Indirect Costs
- I: Total Direct and Indirect Institutional Costs (G+H)
- J: Fee
- K: Budget Justification

The NIH application breaks these sections into three separate screens as you complete the form online:

- Screen 1: Sections A and B (Personnel)
- Screen 2: Sections C, D and E (Equipment, Travel, and Trainee Costs)
- Screen 3: Sections F through K (Other Direct and Indirect Costs and the Budget Justification)

Now, let's examine each of these sections by screen.

Start With Personnel

NIH devotes the two sections on the first screen to detailing your proposal's personnel needs.

Direct from NIH:

A. Senior/Key Person

This section should include the names of all senior/key persons at the applicant organization who are involved on the project in a particular budget year. Include all collaborating investigators, and other individuals meeting the senior/key person definition if they are from the applicant organization. Details of collaborators at other institutions will be provided in the Subaward budget for each subaward/ consortium organization. Personnel listed as Other Significant Contributors who are not committing any specific measurable effort to the project should not be included in the Personnel section of the budget since no associated salary and/or fringe benefits should be requested for their contribution. Consultants designated as senior/key persons in the Senior/Key Person Profile Form can be included in Budget Section A only if they are also employees of the applicant organization. Otherwise, consultant costs should be included in Consultant Services.

What this means:

This section offers a series of data fields for each Senior/Key Person, including the following:

- First, middle and last name, along with any prefixes or suffixes
- Project role — identify each Senior/Key Person, including project directors/ principal investigators, postdoctoral associates and other professionals
- Base salary — enter the annual compensation paid by the employer
- Calendar, Academic or Summer months — indicate the number of person months devoted to the project for each individual (based upon the appropriate calendar, academic or summer designations)
- Requested salary — regardless of the number of months each Senior/Key Person devotes to the project, you must identify only the salary amount you are requesting for this budget period
- Fringe benefits — enter the cash value of any applicable fringe benefits for each person. According to the NIH: the fringe benefits rate is based on your institution's policy; the NIH does not have a pre-set limit on fringe benefits. More information on what is included as fringe benefits can be found in the Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2013/ nihgps_ch7.htm#Fringe_Benefits. If you have questions about what rate to use, consult your institution's sponsored programs office.)
- Funds requested — here, note the requested salary and fringe benefits.

For Section B (Other Personnel) on this application budget screen, you will identify the number of people in each project role rather than name individuals. In fact, Section B includes the following data fields for each role:

- Number of personnel — identify the number of people you are proposing for each project role category
- Project role — the form already lists Post Doctoral Associates, Graduate Students, Undergraduate Students and Secretarial/Clerical, and you should count only those not already listed in Section A. You can list additional

project roles in the additional data fields provided.

- Calendar, Academic or Summer months — indicate the number of person months devoted to the project for each project role category (based upon the calendar, academic or summer designations)

- Requested salary — show the amount of salary/wages you are requesting for each project role

- Fringe benefits — enter the cash value of any applicable fringe benefits for each project role

- Funds requested — note the requested salary and fringe benefits for each project role

Screen 2 Means Direct Expenses

NIH devotes three sections on the second screen to specifics regarding any equipment, travel and support costs associated with your proposal.

For Section C, you will separately list any equipment costing more than $5,000. NIH defines equipment as "an item of property that has an acquisition cost of $5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year." The agency further notes that it will allow items limited to research equipment and apparatus that you do not already have available to conduct your work. And it usually will not cover general-purpose equipment, such as personal computers, unless you use them exclusively or primarily for conducting your proposed research.

In this section, you also have to list the estimated cost of each piece of equipment, including shipping and any maintenance costs and agreements.

In Section D, you must outline your travel costs. There are separate data fields for domestic and foreign travel, which NIH breaks down as follows:

- Domestic travel — In this field, include the total funds you are requesting for travel within the United States, Canada, Mexico and U.S. possessions.
- Foreign travel — Here, you list the total funds you request for travel beyond North America and U.S. possessions.

For both types of travel, you must note in your budget justification document the purpose, destination, travel dates (if known) and number of individuals for each trip. If you do not know when the travel will take place, you must estimate the trip's length (for example, three days).

And although the application includes Section E for participant/trainee support costs, NIH states the following:

Unless specifically stated otherwise in an announcement, NIH and other PHS agencies applicants should leave blank Section E. Note: Tuition remission for graduate students should continue to be included in Section F. Other Direct Costs when applicable.

At the same time, if you must complete this section, you will provide the total requested funding amounts related to participants and trainees involved in your project for tuition/fees/health insurance, stipends, travel and subsistence, among others.

Keep Track of Other Direct Costs

The third screen of the detailed budget form includes Sections F-K, which consist of the remaining costs associated with your proposed research.

NIH reserves Section F for Other Direct Costs. This is where you must detail the following:

- Materials and supplies — Here, you note general categories

- Publication costs

- Consultant services

- ADP/computer services

- Subawards/consortium/contractual costs

- Equipment or facility rental/user fees

- Alterations and renovations

- Other, which might include such costs as patient care and tuition remission.

For Section G (Total Direct Costs), you report the sum of the totals for Sections A-F.

In Section H, however, you will provide information regarding Indirect Costs, breaking them down by type, such as salaries and wages. Keep in mind that your institution should have this information because it usually contracts with NIH for an indirect cost rate that applies to all research conducted at the organization.

For Section I, Total Direct and Indirect Costs, you simply add the totals for Sections G and H. And Section J (Fee) is usually left blank because a fee is generally not allowed on a grant unless specifically noted in a program announcement. In that case, you should enter the requested fee.

Finally, Section K is the Budget Justification.

Direct from NIH:

Use the budget justification to provide the additional information requested in each budget category identified above and any other information the applicant wishes to submit to support the budget request. The following budget categories must be justified, where applicable: equipment, travel, participant/trainee support and other direct cost categories. Only one file may be attached. The attachment is required.

Use this section to list the names, role (e.g., PostDoc or Graduate Student), associated months, salary and fringe benefits for all Postdoctoral Associates and Graduate Students included in Budget Section B. Other Personnel.

Include a justification for any significant increases or decreases from the initial year budget. Justify budgets with more than a standard escalation from the initial to the future year(s) of support. Also use this section to explain any exclusions applied to the F&A base calculation.

If the application includes a subaward/consortium budget, a separate budget justification is submitted for that budget. See Section 4.8 Special Instructions for Preparing Applications with a Subaward/Consortium.

What this means:

Section K is a single narrative that you will upload to support the need for the requested funds in your application's detailed budget from Sections A-J. And you have to address each cost individually.

STRATEGY:

The budget narrative can be your opportunity to expand upon your proposal without affecting your scientific content related to explaining your research.

Because most PIs focus on their science, they frequently wait until the last minute to write the budget justification. But this is your chance to expand upon the project without taking up precious pages in the Research Strategy. In fact, the budget narrative does not count against your application page limit. Therefore, it can be your opportunity to expand upon your proposal without affecting your scientific content related to explaining your research. However, the budget justification should not include anything not stated in the narrative as reviewers may not read it in detail.

This budget justification also allows you to show reviewers that you have adequately planned for your project, you have done this before, and you know what you are doing. To support this, make sure that your justification matches your overall project narrative. These two items should go hand-in-hand because you do not want a reviewer to be surprised to find an item in the budget that is not

mentioned in the research strategy. The two budget justifications from successful NIH R01s provided earlier in this chapter are examples of K forms.

On the other hand, if you are submitting a revision or supplemental application, you only need to include those budget items for which you request additional funds. And NIH says that if the initial budget period of the supplemental/revision application is less than one year, you can prorate the personnel costs and other appropriate items in your detailed budget.

NIH Has Special Instructions for Subaward/Consortiums

If your application includes a subaward or consortium agreement, NIH requires each consortium grantee organization to complete a subaward/consortium budget component, which includes a budget justification section. The agency requires this only for those organizations that perform a substantive portion of the project.

And this is necessary only when the prime grantee is submitting a detailed (R&R) budget. This is not needed if you are using a modular budget.

Remember, though, the NIH is expecting someone to be designated as the consortium lead investigator responsible for ensuring proper conduct of the project or program at that site. However, when completing the Project Role for the consortium lead investigator, the project role of "PD/PI" should only be used if the entire application is being submitted under the Multiple PI policy.

Subawards for social and behavioral science projects would include the following types of institutions:

- **Partner universities where co-PIs work.** For example, your project may include five sites throughout the country conducting similar kinds of research. Each institution would budget for the salaries of the co-PI, research assistants, supplies and equipment at that university.

- **Research firms that carry our part of the project.** For example, several of the projects used as examples in this manual contract out their survey research to another institution. There would be a separate budget form for each of these subawards.

- **Clinical institutions or community based institutions that conduct a component of your project.** For example, if you are conducting a test of an instrument developed as part of the project, the hospital or clinic conducting the test may have its own staff, participant recruitment, supply, data storage and related costs. If you are working with a coalition of community based organizations to train local community residents to conduct research and manage that research process, you would have a budget for the research staff costs, personnel to train and manage community based researchers, data collection supplies, data storage, and other related costs in a subaward budget.

- **Project evaluation contractor or contracting firm.**

Institutions Have Deadlines, Too

Most universities and other grant-seeking organizations will not allow you to wait to submit your budget. Usually, they set a deadline of three or four weeks before the NIH submission date for you to give them your proposed budget, including all the appropriate sign-offs and consortium agreements.

In fact, many experts suggest that you address your budget as soon as you outline your grant proposal to ensure you complete it on time.

Therefore, you should check with your grants submission department to ensure you correctly understand all the institution-specific applicable deadlines for your application.

TIP:

Many experts suggest that you address your budget as soon as you outline your grant proposal to ensure you complete it on time.

CONCLUSION

Whether you request a modular or detailed budget for your R01 application, your financial planning to support your research likely should fall within the early stages so you can complete it on time — either to meet your institution's deadlines or those for NIH.

And although modular budgets may appear easier to plan, you are limited to no more than $250,000 per year in direct costs attributed to your proposal. Alternatively, you can request more funds with detailed budgets, but the planning process is more intensive and time-consuming.

In either case, how you explain your monetary request plays a key role in NIH's funding decision because the justification narratives may be studied at multiple levels of the agency's review process.

Keep in mind also that although reviewers are not supposed to include the budget as part of their overall assessment of your application, they may use it to judge your proposal's feasibility. Therefore, you should consider it a key portion of your application.■

Your Notes:

Chapter 8:
Submitting Your Application

Before you submit your R01 application, take time to review the finished product. Make sure your proposal works as a whole rather than a group of parts. Remember your ultimate goal is to communicate that your research deserves funding, you're the right person to conduct it, and your institution is the right place to do it.

That's why reviewing your proposal for content is important. Ensure all of the sections communicate your message adequately. Your research strategy must include strong Specific Aims and address your project's significance, innovation and approach. Your project summary should be a compelling synopsis of your proposed research. And your budget should be in synch with your research strategy.

Reviewing your proposal for writing quality is just as important. You may want to ask colleagues or non-experts to read your proposal and provide feedback. Or you may need to hire a professional editor.

You must also construct a cover letter to introduce your proposal. This is part of the National Institutes of Health's (NIH's) application upload process, and the agency encourages you to include one. If you are submitting a changed or corrected application, the cover letter is mandatory.

In addition, make sure you have included all of your application's necessary components. Don't forget any attachments, and confirm that all attachments adhere to NIH requirements. The agency used to provide a two-day window during which applicants could fix errors, but that is no longer available. Therefore, it is extremely important to ensure all of your documents are uploaded.

TIP:

Your Research Strategy must include strong Specific Aims and address your project's Significance, Innovation and Approach.

Include All the Necessary Components

Arguably the most important step in reviewing your R01 application is making sure it is complete. There are certain components that are mandatory for all applicants, and there are parts that are required only under certain circumstances.

Direct from NIH:

A completed application includes data in the following components:
Required Components

- SF424 (R&R) (Cover component)
- Research & Related Project/Performance Site Locations
- Research & Related Other Project Information
- Research & Related Senior/Key Person
- PHS398 Cover Page Supplement
- PHS398 Research Plan
- PHS398 Checklist
- PHS398 Modular Budget or Research & Related Budget, as appropriate

Optional Components

- PHS398 Cover Letter File
- Research & Related Subaward Budget Attachment(s) Form

For certain applicants, NIH requires additional components. You must take extra steps if your research involves multiple institutions or requires multiple principal investigators (PIs). The same is true if you are submitting a revision application or if you belong to a foreign institution applying for U.S. dollars.

Foreign Organizations

Applicants from foreign organizations must:

- Prepare their budgets in U.S. dollars
- Create detailed budgets for all applications (complete the research and related budget component of the SF424 application forms, not the PHS398 modular budget component)
- Omit any charge-back of customs and import fees
- Comply with the format specifications, which are based upon a standard U.S. paper size of 8.5" x 11," within each PDF
- Facilities and administrative (F&A) costs should be 8 percent of your total direct costs, less equipment
- Comply with federal/NIH policies on human subjects, animals and biohazards
- Comply with federal/NIH biosafety and biosecurity regulations

Applications With Multiple PIs

If your project has multiple PIs, one of you must be the primary NIH contact. This person is responsible for all communication, for assembling the application materials and for coordinating progress reports. At the same time, this PI may not have other special roles or responsibilities within the project team.

The contact's information should be entered on the SF424 (R&R) cover component. All other PIs should be listed in the research and related senior/key person component as PIs. The commons (login) ID of each PI must be included in the credential field of the research and related senior/key person component. If it is not, NIH will reject the application.

You must also include a multiple PI leadership plan. The plan should describe your rationale for having more than one PI as well as the leadership team's organizational structure. You should detail communication plans, the decision-

REMEMBER:

The primary PI is responsible for all communications, for assembling the application materials and for coordinating progress reports.

making process for scientific direction and procedures for resolving conflicts. If you have planned budget allocation, you should describe how resources will be distributed to the project's specific components or individual PIs.

Applications Involving Multiple Institutions

When multiple institutions are involved in a project, you must designate one as the prime institution. This facility must administer a subcontract to request funding for the other(s).

The prime institution should submit a detailed budget using the research and related budget component. Attach all of the other facilities' budgets separately to the research and related subaward budget attachment(s) form.

For a modular budget, the prime institution completes the PHS398 modular budget component only. The facility must then provide information concerning the consortium/subcontract budget in the budget justification. Separate budgets for each consortium/subcontract grantee are not required.

Revision Applications

A revision application is a competing supplemental application that asks for support for a significant expansion of your project's scope or research protocol. If you're submitting one, don't forget these requirements:

- A one-page introduction — "Introduction to application" section of the PHS 398 research plan — describing the supplement's nature and the impact it will have on your original proposal
- Adequate details from the original application for reviewers to evaluate the revision in the context of the original
- Budgetary changes for the remainder of the current grant's period
- A specific response to criticisms in the prior summary statement

The NIH cautions:

> Applications for revisions are not appropriate when the sole purpose is to restore awards to the full SRG-recommended level if they were administratively reduced by the funding agency. A revision application should not be submitted until after the original application has been awarded and must not extend beyond the term of the current award period.

Resubmitted Proposals

Most NIH R01 proposals are not funded on the first try. As of April 16, 2014 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html) NIH now allows an unlimited number of resubmissions based on your original research idea. Unless you have significantly changed your aims and goals, you should use the same title for a resubmission as in your original application. For more detailed advice on revising and resubmitting your proposal, see Principal Investigators Association's guide Revising and Resubmitting NIH Proposals, https://principalinvestigators.org/product/revising-and-resubmitting-nih-proposals-guide.

If you are resubmitting an R01 application that has been previously reviewed but not funded, you will also need to include an additional element. A resubmitted grant is similar to a regular proposal, with two important differences. The revised proposal requires a one page introduction that explains how the investigator has revised the grant. This is the formal place to respond to comments from the reviewers. Details for writing a successful introduction will be discussed later in this manual.

Not counting the introduction, a revised proposal must keep to the same page limits as other proposals. This means that the grant needs to keep all of the elements that the reviewers liked in the original grant, plus add any changes or clarifications while staying within the page limits. NIH and reviewers recommend marking text that is changed within the grant in some way, usually either using italics, bold font or putting a line on the side of the paragraph with new text.

REMEMBER:

The revised proposal requires a one page introduction that explains how the investigator has revised the grant.

REMEMBER:

Not counting the introduction, a revised proposal must keep to the same page limits as other proposals.

ENSURE ALL ADDITIONS ARE ATTACHED AND COMPLY WITH GUIDELINES

Just like the application components, some additions are mandatory for all applicants, and others are required only under certain circumstances.

Conditional additions include documents that describe the use of consultants, consortium/contractual arrangements, plans for resource sharing, how you will handle select agents and how you plan to protect human subjects. Reference letters are also required conditionally.

Conversely, all applicants must include additions describing facilities and other resources, as well as a bibliography. If your research requires documents such as informed consent forms or surveys, you must include them in an appendix.

Appendix Materials

The appendix should only contain supportive or supplemental information. Do not include essential information in the appendix in an attempt to circumvent the research plan's page limitations.

You are allowed a maximum of 10 PDF attachments. If you require more than 10, you can combine the information into attachment No. 10.

TIP:

Do not include essential information in the appendix in an attempt to circumvent the research plan's page limitations.

New, resubmission, renewal and revision applications may include the following materials in the appendix:

1. Although publications are not allowed as appendix materials in most cases, applicants may sometimes submit up to three of the following types of publications:
    a. Manuscripts and/or abstracts accepted for publication but not yet published.
    b. Manuscripts and/or abstracts that have been published, but a free, online, publicly available journal link is not available.
    c. Patents directly relevant to the project.

Do not include unpublished theses or abstracts/manuscripts submitted (but not yet accepted) for publication.

2. Clinical protocols, informed consent documents and data collection instruments such as surveys and questionnaires
3. For materials that cannot be submitted electronically or materials that can- not be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), contact the scientific review officer (SRO) for instructions. Be as concise as possible, and submit only information essential for the application's review.

Do not include these items in the appendix:

1. Photographs or color images . You must include these images in the research strategy PDF. However, images embedded in publications are allowed.
2. Publications that are publicly accessible. Include the URL or PubMed sub- mission identification numbers in the bibliography, the progress report publication list section or the biographical sketch section.

Bibliography

There is no specific format to which your bibliography must adhere. Just ensure that it includes all references cited in the research plan, and references are arranged in the same sequence as they appear in the document. Each listing must include the names of all authors, the article and journal title or the book title, the volume number, page numbers and year of publication.

Only include bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon when preparing any application section.

The location of this information is slightly different in the SF424 R&R and the PHS398. Be sure to read the application instructions carefully for the application you are using.

Facilities and Other Resources

Make sure you have identified the facilities you will use (computer, office, clinical and other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and availability to the project. Describe only those resources directly applicable to your work.

Consortium/Contractual Arrangements

Explain the programmatic, fiscal and administrative arrangements between the applicant organization and the consortium organization(s).

This document could be labeled the "Research Plan" or "Consortium Agreement." It usually includes a brief narrative explaining who is involved in the project and their roles in the project. Often, these documents include diagrams or flow charts showing how the various institutions relate to each other and various research partners will work together to complete the project. While there is no page limit for this document, it should be brief and clearly written.

For social and behavioral science projects these relationships can take several forms. They may include several universities or research centers that are each performing part of the research or you may partner with organizations that provide direct services or health care. If you are doing a project that involves a medical facility as a clinical partner, you will need to describe if that facility is an active participant in the research or just hosting your research.

Active participation would mean that staff from the hospital or clinic would be part of your research team. In a hosting relationship, your team performs research at a facility that agrees to give you access to potential study participants and otherwise facilitate your work. For instance, if you are doing a study of caregivers of people with advanced kidney disease, you might partner with a hospital with a large transplant program and a dialysis unit. If the hospital was an active partner, a doctor from the kidney transplant and/or dialysis units may be a part of your research team responsible for recruiting caregivers for the study, analyzing the results, and translating the findings into practice. You would need to explain her role as a team member and the contractual agreement you have with the hospital. If the hospital was simply hosting the research, they might give your staff access to the list of patients or their caregiver support group and develop a joint consent form that allows your staff to access patient medical records as per HIPAA guidelines. In this case you would need a support letter explaining the hospital's commitment to work with you on the project and you would need to explain the nature of your agreement with the hospital in your consortium/contractual agreement document.

Researchers may have similar relationships with community based organizations or umbrella organizations for organizations in the community. For example, the DO DEPARTMENTS OF PARKS AND RECREATION FOSTER OR ALLEVIATE HEALTH DISPARITIES? project partners with an umbrella organization that represents parks throughout the country. This organization committed to help the study team conduct the research in several ways. As with medical facilities, community based organizations (CBO) can be either active participants or project hosts. This would need to be explained for each

organization. For CBOs, it is also helpful to include a sentence explaining what the organization does and why it would be a good partner for this project.

Often, projects include both active partners and organizations hosting research. For example, a study of the social networks of transitioning youth with autism might have research faculty from two universities participating in the project, as well as staff from a large youth serving organization. These three institutions would be active partners in the consortium. The project may also have agreements with five smaller organizations providing youth transition services that would simply host researchers and facilitate their access to families who would be invited to participate in the study.

Consultants

Attach letters from all consultants that confirm their project roles. The letters should include the charge for consulting services. Sometimes consultant letters are also support letters and are included in the support letter section.

Protecting Human Subjects From Risk

NIH will not distribute awards unless human protection assurances are on file with the Office for Human Research Protections (OHRP). However, it is important to note that your grant does not have to have IRB approval before you apply for funding. In fact, it is often wise to wait if you are developing a new project as your design may change if it needs to be submitted several times before it is funded. Your IRB committee will want to see the close to final versions of consent forms, questionnaires and other research protocols. IRB approval is usually only good for one year, so if you have approval before submitting, it may have expired by the time your project receives funding. For more information on IRB procedure, see Qualitative Research & IRB: A Comprehensive Guide for IRB Forms, Informed Consent, Writing IRB Applications and More
https://principalinvestigators.org/product/qualitative-research-irb/.

Resource-Sharing Plan(s), Including Data-Sharing Plans

You must share final research data for applications that seek $500,000 or more in direct costs in any year of the grant. The same is true for some program announcements and all genome-wide association studies. Describe your resource-sharing plan — or justify its absence — in a brief paragraph in your research plan.

Select Agents

Have you identified any select agents to be used in the proposed research?

These are hazardous biological agents and toxins the U.S. Department of Health and Human Services (HHS) or U.S. Department of Agriculture identify as able to pose a severe threat to public health and safety, animal and plant health, or animal and plant products.

If your proposed research involves using select agents, your application has to detail how you'll use them. But how can you best convey to reviewers that you've thoroughly considered safely handling these dangerous substances? Following these recommendations can help:

- Resist the temptation to merely "touch up" the boilerplate language your university provides. True, customary information from your institution gets you started. But reviewers are looking for more than that. They want your plan's specific details.
- Double-check information security. Regulators want to know you'll protect against accidental release of agents that can harm people, animals and plants. They also recognize that some of the biohazards have the potential for bio-terrorism. So outline your information security measures.
- Explain your backup plans. Reviewers know what can go wrong and want to know that you've considered it. A short description addressing common problems goes a long way toward establishing your credibility.

- Focus on existing facilities, equipment and experience. Lacking any of these will hurt you. NIH doesn't want to pay for your learning curve or expensive facilities.

Reference Letters

As discussed in chapter 3, reference letters are extremely important for behavioral and social science proposals. You will need support and reference letters from any person or organization participating in the project. It may also be helpful to get one or two general support letters from an advocacy organization or professional organization affiliated with your research that thinks it will benefit from your research and would help disseminate findings to a clinical or practitioner audience.

Note there are two types of reference letters:

1. A letter of recommendation is from a faculty member or other person qualified to evaluate your proposal's merit and your qualifications.
2. A letter of support is typically from an outside individual whose assistance you will need to ensure your project's success. This letter is meant to establish your credibility, convince the review board your project is feasible and detail the type of support promised.

You can only include reference letters if they are specifically requested in the funding opportunity announcement (FOA) or application guide. You can submit them as soon as the FOA opens, even prior to sending in your application.

Reference letters are linked by FOA number and your Commons user ID. If you don't provide these values or enter them incorrectly, the letter never connects to the application. Orphaned letters are deleted from eRA Commons after six months.

If you are submitting a changed or corrected application to address eRA-identified errors/warnings, the reference letters will automatically move to the most recent application submission for a specific opportunity deadline. Reference letters that come in electronically must be uploaded electronically via eRA Commons.

If your original application was rejected, and you decide to resubmit as an A1 application, you cannot use the same reference letter(s). You must submit new ones for each opportunity.

Unless stated, the aforementioned attachments do not influence your application's rating (priority score). Your reviewers will comment on the attachments' adequacy, however. Any concerns they have may negatively affect and postpone an award.

Frequently Asked Questions About Attachments

Q. What type of attachments does NIH accept?

A. PDFs. But if an attachment can't be submitted electronically, the agency will accept a hard copy.

Q. Who is responsible for generating the PDF documents?

A. The applicant or his institution's grant office.

Q. How does an applicant submit appendix material that he cannot send electronically?

A. Mail "hard" appendix materials, such as a video, to the SRO and then the reviewers.

Q. How does NIH accommodate appendix material?

A. There is an attachment upload available. You can include up to 10 separate PDF attachments. The appendix attachment upload feature is in the PHS 398 research plan component.

Q. How does NIH accommodate supplemental/additional/correction material submitted after the application?

A. Supplemental/additional/correction material must be submitted through, and at the discretion of, the assigned SRO. Some FOAs prohibit the submission of supplemental/additional/correction materials.

Q. How does the NIH handle administrative supplements?

A. Individual Institutes and Centers handle them.

CREATE A COVER LETTER

Although it's not always required, NIH strongly recommends that you submit a cover letter with your grant application. Keep in mind the agency likely will use the letter to help assign your proposal to the right study section.

For social and behavioral science proposals, the cover letter is extremely important and PIs need to do their homework before writing it. This includes doing research on which study sections would be best to review your application by looking at both the names of the study sections and the rosters of people on them. The Center for Scientific Review publishes the rosters for study sections at https://public.era.nih.gov/pubroster/. Do some background research through Google Scholar or looking up their academic profiles on the people named for the study sections you think would be appropriate to find out both their methods expertise and any other information that might be helpful about their background. You may also note in identifying study sections that someone who is a clear competitor or doesn't like your approach to studying a certain topic is on the review panel. If this is the case, you can ask that this person be recused from reviewing your proposal.

Your cover letter should include the following elements:

1. **The title of your proposal and its primary goal using keywords that will help identify the appropriate study section for review.**

2. **If your proposal is responding to a specific RFA, name that RFA and its number.**

3. **The name of the program officer you talked to in developing your grant and their Institute.** If you want the proposal considered by several Institutes and Centers, include the name of each of those ICs. To quote one program officer *"... name the program official you talked to. That helps get it to the right Institute."*

4. **Identify the study section you would like to review your application.**
   CSR is not required to honor your request, but they will often try to do so. Once your application has been accepted, you will be able to see what study section it has been assigned to. If you find it has been assigned to a study section with no expertise on your methods or approach, program officers explain that you can: *"Ask for a different study section. Write to the SRO if you see that its been assigned wrong. I wish people did that more. Pay attention to where your application is assigned."*

5. **Identify people on the study section that you would like recused from reviewing your proposal.** This is usually done in a few sentences explaining why this person would have a conflict of interest and should not be part of the review panel. Conflicts of interest can occur because you are already working with this person on this project or another one or the person is a competitor. You can also request recusal for conflict of interest if the person is known to support a theoretical or methodological approach different from yours and has criticized your approach in publications or documented presentations.

6. **Specify the kinds of methods you plan to use.** This will also help the CSR find reviewers who have the expertise to review your proposal. As one program officer commented: "[You] *need to be clear in the cover letter about type of methods and ask for expertise on [the review] committee that can handle it. The review office will definitely work to find people knowledgeable on the study section (could be guest reviewer) that understands [your] methodology."* The CSR will likely pay attention to these requests because you can ask for automatic reconsideration if it is clear that everyone on the committee reviewing your proposal knew nothing about your methods or approach.

Direct from NIH:

The cover letter is only for internal use and will not be shared with peer reviewers. The letter should contain any of the following information that applies to your application:

- Application title
- Funding opportunity (PA or RFA) title of the NIH initiative
- Request of an assignment (referral) to a particular awarding component(s) or Scientific Review Group (SRG) [PHS (Public Health Service) makes the final determination.]
- List of individuals (e.g., competitors) who should not review your application and why
- Disciplines involved, if multidisciplinary
- For late applications, include specific information about the timing and nature of the cause of the delay
- When submitting a Changed/Corrected Application after the submission date, a cover letter is required explaining the reason for the Changed/Corrected application. (If you already submitted a cover letter with a previous submission and are now submitting a Changed/Corrected Application, you must include all previous cover letter text in the revised cover letter attachment. The system does not retain any previously submitted cover letters until after an application is verified therefore, you must repeat all information previously submitted in the cover letter as well as any additional information.)
- Explanation of any subaward budget components that are not active for all periods of the proposed grant
- Statement that you have attached any required agency approval documentation for the type of application submitted (This may include approval for applications $500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or U13), etc.)

Your cover letter can also include requests for peer review assignment. The Division of Receipt and Referral, Center for Scientific Review, is responsible for assigning applications to institutes/centers and SRGs. The division asks that applicants make requests in the following format:

- List one request per line.
- Place the institute/center and SRG review requests on separate lines.
- Place positive and negative requests on separate lines.
- Include the name of the institute/center or SRG, followed by a dash and the acronym. Do not use parentheses.
- Provide explanations for each request in a separate paragraph.

STRATEGY:

Although you should never request individual reviewers by name, you can ask for those with a specific area of expertise.

Making Peer Review Suggestions

There are tips you should keep in mind when making peer review suggestions in your cover letter. First, never request individual reviewers by name. But you can ask for reviewers with a specific area of expertise.

Analysis has shown that requests for expertise (as long as reviewers go unnamed) are a valuable source of information when NIH selects peer reviewers. When you make this suggestion, you can include any of the following:

- Suggestions of study sections or funding agencies best suited to a proposal. Include advice you received from a program director or SRO about a study section or institute.
- For multidisciplinary applications, highlight the application's main disciplinary/methodological thrust.
- Include a list of research disciplines critical to understanding your application.

It's also perfectly acceptable for you to learn about peer reviewers by viewing SRG rosters at http://era.nih.gov/roster/. But you should never communicate directly with a review group member about an application, either before or after review. Peer reviewers must report to SROs any direct or attempted contact by applicants.

Communicating Conflict of Interest

Include information regarding a conflict of interest, or a potential conflict in your cover letter. For example, say you request a specific study section to review your application. But the roster indicates that a direct competitor, a former mentor or a former student is a member of that study section. To request the exclusion of a reviewer:

- List the individual in the cover letter.
- Provide a brief description of why the person should not be involved in reviewing your application.

Cover Letter Template

NIH offers the following template as a guide for creating a cover letter.

Application title.

Funding Opportunity Announcement number:

Please assign this application to the following: Please note the outline of indentations.

Institutes/Centers
    National Cancer Institute – NCI
    National Institute for Dental and Craniofacial Research – NIDCR
Scientific Review Groups
    Molecular Oncogenesis Study Section – MONC
    Cancer Etiology Study Section – CE

Please do not assign this application to the following:
    Scientific Review Groups
        Cancer Genetics Study Section – CG

The reasons for this request are [provide a narrative explanation for the request(s)]. List of individuals (e.g., competitors) who should not review the application and why.

Disciplines involved, if multidisciplinary.

Statement that required NIH approval documents are included. (e.g., budget over $500K/year; approval for conference grant; cooperative agreement, etc.) For late applications, if applicable, include explanation of the delay as part of the letter.

Here is an example of a cover letter from an application recently submitted to NIH. Identifying characteristics have been changed as the proposal is currently under review:

9/22/2014

Center for Scientific Review

National Institutes of Health

Suite 1040

6701 Rockledge Drive MSC 7710

Bethesda, MD 20817

Dear Members of the Center for Scientific Review,

On behalf of my research team at University, I thank you for the review of our proposal entitled "Project Title" for the October, 2014 submission cycle. This proposal is in direct response to the Funding Opportunity Announcement PAR-13-289 entitled "Building Evidence: Effective palliative/End of Life Care Interventions (RO1) of the National Institute of Nursing Research. I request a secondary assignment to the National Cancer Institute within their Palliative Care Research Portfolio. I have been in communication with Dr. [Program Officer], Chief of the Office [branch], who has expressed great interest in this proposal and encouraged our submission.

Our research team believes that this study of family caregivers of patients with [specific type of] cancer, given the mortality rate associated with the disease and the compressed illness-dying trajectory, will be generalizable to other cancers with a compressed illness trajectory. Based on a mixed methods approach and longitudinal data, we will have a strong empirical foundation to develop palliative care and end of life interventions based on a set of core outcomes measured from diagnosis with advanced cancer through bereavement.

Thank you for your consideration of this application.

Sincerely,
[PI name], PhD, ARNP, ANP-BC, ACHPN, FAAN
Professor and [endowed chair] Faculty Scholar

REVIEW YOUR PROPOSAL FOR CONTENT

So you've assembled the necessary components, included the required attachments and written a comprehensive cover letter. Now, it's time to review your proposal's content. Examine the most important sections closely. Ensure your abstract is a compelling, detailed summary of your research. Make certain your budget is in synch with your research strategy. Evaluate your specific aims, and assess how you've described your project's significance, innovation and approach.

Project Summary/Abstract

Your project summary should succinctly describe every major aspect of your project. But it should not exceed 30 lines. If an abstract is too long, NIH will flag it as an error.

Your project summary must include these parts.

- A brief background of the project
- Specific aims, objectives or hypotheses
- The significance of your research and its relevance to public health
- Your project's unique features and innovation
- The methodology (action steps) to be used
- Expected results
- Description of how your results will affect other research areas

Remember that your abstract is the first component reviewers read, and it may actually be the only part they read. It sets the tone for your application and should be a good predictor of the proposal that follows. It also becomes the primary identifier for your project and may be used for public dissemination in the future.

REMEMBER:

Your Abstract is the first component reviewers read, and it may actually be the only part they read, setting the tone for your entire application.

Make sure your project summary:

- Follows the proposal's logic and order
- Is composed of short, direct sentences
- Clearly details your hypothesis
- Has been proofed and edited rigorously

Don't:

- Just cut and paste sections from your proposal
- Forget to describe the problem
- Include too much obvious background information
- Use jargon, acronyms, symbols and abbreviations
- Include figures, tables or references

STRATEGY:

Tell reviewers why your research goals are worth NIH's money, why you are the person to do it and how your institution can give you the support you'll need to get it done.

Budget

Your budget tells reviewers more than just how much money you want. Make sure it accurately reflects the resources you will need and the expenses you expect to incur. Were you realistic in your request? Both padding and deliberately under-budgeting reflect naiveté, and reviewers will notice.

Special forms are provided for the budget and justification. NIH recommends the budget and justification cover personnel, consultants, equipment, supplies, travel and other expenses (for example, participant incentives). Make sure you provided brief descriptions of duties for all budgeted positions, with the number of person- months requested each year and any anticipated fluctuations. Try to eliminate as many "to be named" personnel designations as you can. They're often deleted by reviewers.

If you use a modular budget, you do not need to detail supplies, equipment and travel costs. But for non-modular budgets, make sure you justified all equipment purchases. Details are important, especially for non-project specific equipment, such as a fax machine and computers.

Also, be sure to check indirect costs. Some institutions have on-campus and off-campus rates. Your budget will also need to reflect institutional policies for costs related to graduate assistants like tuition and course release costs. Your budget and budget justification will also need to note any in-kind matches such as donating the cost of a graduate assistant or work study student to work on your project.

Your institution's budget department or your department or center's administrative staff will help you prepare the budget. It will be reviewed and approved by your institutions budget or sponsored research office. These budget staff can answer any questions or concerns regarding the development of your budget. Requirements and terminology tend to differ from agency to agency and award to award. For example, a PI may only have experience measuring effort in percentages. Therefore, the NIH approach of measuring effort in "person-months" may prove confusing.

You should also verify cost estimates with internal and external experts. This can help you accurately estimate and plan project tasks (for instance, international travel considerations, conference venues and equipment quotes).

Reviewing your budget and the project description simultaneously can be helpful as well. This ensures your project scope does not exceed the agency's maximum budget request.

Research Strategy

The Research Strategy is organized into three sections: Significance, Innovation and Approach. Reviewers' assessment of these sections will largely determine whether your application is recommended for funding.

Ensure all sections are internally consistent and dovetail each other. Did you use a numbering system and make sections easy to find? Did you lead the reviewers through your research plan? Make sure your research strategy section answers these questions:

REMEMBER:

Some grant programs are subject to legislatively imposed salary limitations, and any salary limit adjustments are made at the time of award. Compensation includes salary or wages, fringe benefits and tuition remission.

- What do you intend to do?

- Why is it worth doing? What is the research's significance? How is it innovative?

- What have other researchers done in this field? Use appropriate references. What will your work add to the field of knowledge?

- What have you (and your collaborators) done to establish your project's feasibility?

- How will you accomplish the research? Who will do it, where will they do it, and when?

- What is the expected impact of your research on health and public health

Specific Aims

For the section on Specific Aims, make sure you include a brief narrative describing your project's long-term goals or objectives and your hypothesis. Then follow with your list of aims.

You should only include three or four. That's because one or two aims likely will not have a broad enough scope to provide any real impact on a field. But more than four aims will be difficult to fully develop.

In crafting an effective and convincing Specific Aim, consider the aim's characteristics and its relationship to the others. It is best if one aim is not strictly dependent on the success of the others. If your aims are sequential, tell the reviewers what you intend to do if you get an unexpected result in the first one — that is, why the whole project would not collapse.

Significance

Ensure you cover the state of existing knowledge, including literature citations and highlights of relevant data. You should also include the proposed research's rationale, any knowledge gaps the project will fill, and the potential contribution your research will make to science and public health.

As explained in chapter 5, clearly state what is significant about your research. You want to point out what you are going to achieve that's different from other research projects. You should tell a story about why your research is significant, using relevant citations to show your knowledge of the literature.

Innovation

This section should explain why your concepts and methods are novel. Focus on innovation in study design and outcomes. And summarize findings to be presented as preliminary data in the Approach section.

Keep in mind that a reviewer's response to scientific innovation will vary. This will depend upon how extensively he has read in his own field, how broadly his knowledge extends to other fields,   and how much novelty and risk he is willing to tolerate.

Reviewers tend to be on the conservative side when it comes to awarding grants. They hesitate to support work at the earlier, potentially more innovative stages. Science that is truly revolutionary threatens the existing order, putting at risk the significance and validity of current dogma.

Additionally, reviewers often believe a grant must have enough preliminary data to eliminate significant uncertainty about the central hypothesis or research question but not so much that further investment won't yield additional high-impact papers.

Approach

This section should include the following:

- Your preliminary studies, data and experience relevant to the project design
- An overview of study design
- A description of methods and analyses that will accomplish the project's specific aims
- A discussion of potential difficulties and limitations and how these will be overcome
- Expected results and alternative approaches that will be used if unexpected results occur
- A projected sequence or timetable (work plan)
- If the project is in early stages, a description of any strategy to establish feasibility and the management of any high-risk aspects
- A detailed discussion of the way results will be collected, analyzed and interpreted
- A description of new methodology and why it represents an improvement over the existing ones

Reviewers tend to focus on the Approach section because they can assess logical and technical flaws there more objectively than in other sections.

Last year, NIH's Office of Extramural Research looked at the five reviewing criteria (Approach, Significance, Innovation, Investigator and Environment) and how well scores for each factor correlate with an application's Overall Impact score. The score for Approach turned out to be the best predictor of Overall Impact, correlating to Overall Impact in 82 percent of funded applications.

REMEMBER:

Reviewers tend to focus on the Approach section because they can assess logical and technical flaws there more objectively than in other sections.

The Approach section is also where many new PIs make one or more standard errors that are relatively easy to identify:

- The applicant is "overly ambitious"
- One or more aims are "unfocused" or "underdeveloped"
- An aim is just a "fishing expedition" for a missing gene or interactions
- There's too little description of results analysis
- Over-reliance on a preferred hypothesis
- An aim is just too "risky"

Anticipating these critiques when reviewing your proposal is one of the best defenses you have. Knowing that the Approach score provides the strongest correlation to your Overall Impact rating shows this section is where you should devote most of your reviewing time.

After you've reread your research plan, ask yourself these questions:

- Did you include preliminary data or a progress report?
- Did you avoid excessive experimental detail by referring to publications that describe the methods to be employed? Publications cited should be by you or recognized experts in the field, if possible. For social science proposals, it is often best to cite one publication by you and one by a recognized expert in the field.
- Did you, if relevant, explain why one approach or method will be used over others? This shows you did not simply overlook the alternatives.
- If you're employing a complex methodology for the first time, did you take extra care to demonstrate familiarity with it?
- Did you explain how data will be collected, analyzed and interpreted?
- Did you develop alternative strategies for potential problems?
- Did you include any resource-sharing plans?
- Did you document proposed collaborations and offers of data with restricted availability with letters?
- Did you point out any procedures, situations or materials that may be hazardous to personnel and describe precautions to be exercised?

REVIEW YOUR PROPOSAL FOR WRITING QUALITY

Once you've assessed your application's content, look at the quality of your writing. Does your proposal clearly communicate the message you want to convey? Is it concise and to-the-point? Are there grammatical, spelling or punctuation errors?

Take these NIH-recommended editing steps:

- Allow enough time so you can put the completed application aside and later edit it from a fresh vantage point. You may only need to break for a few hours, or you may need a few days. When you go back to your proposal, try reading it aloud.
- Allow at least a few weeks for an internal review by collaborators, colleagues and mentors. Make revisions/edits from that review. If possible, have experts in your field and those who are less familiar with your science provide feedback. The application should be easily understood by all.
- If more than one investigator has contributed to the application, the writing may not be cohesive. Employ one overall editor to ensure the sections work together.
- Have zero tolerance for typographical errors, misspellings, grammatical mistakes or sloppy formatting. A disorganized application may convince reviewers you will conduct your research in the same manner.
- Perform a final proofread of the entire grant application.

Writing Examples

Unclear writing: "This study will explore the complex ways that social capital influences the future trajectories of youth with ASD through a detailed analysis of the personal social networks of transitional youth and their families as well as the networks of affiliated organizations. This research identifies both beneficial and deleterious effects of social capital through connecting network identities and culturally defined knowledge to outcomes for ASD youth. Providing analysis of

networks subjective constructs will prove an important innovation because cultural constructs influence the ways that knowledge is utilized by youth, their families and institutional actors. Network strength and effectiveness will be analyzed in the context of the kinds of outcomes (for example finding a job, entering a day program, sitting at home with no assistance) that youth achieve within a six month period after finishing high school"

An improvement: "This study will clarify how social networks and organizational connections impact on transition to adult programming that promotes independence and self-sufficiency for youth with autism spectrum disorder (ASD). Following Portes and Bordieu's work on social capital (reference), the study explores both ways that networks help or hinder successful transitions. Successful outcomes include transitioning to a job or day program while negative outcomes include having no programming or inappropriate programming. The project is innovative because it looks at 1) both organizational and individual social networks and 2) examines ways that the quality of relationships with connections and beliefs held by both family members and staff involved in the transition process influence transition choices. Through linking network behavior to outcomes six months after high school completion, the study shows how and why some connections are more effective than others. "

The second example is about the same number of words, but the language is much clearer, spelling out abbreviations and only using the scientific term "social capital" in the context of the literature that identifies which version of social capital the applicant is using. Given that social capital is a contested concept, these kinds of clarifications are important. The second version also uses plain language and keywords like innovation to explain the project's goals.

Further improvement: "This study will clarify how social networks and organizational connections impact on successful transitions of youth with autism spectrum disorder (ASD) to adult programming that promotes independence and self-sufficiency. Following Portes and Bordieu's work on social capital (reference), the study explores how networks help or hinder successful transitions.

Successful outcomes include transitioning to a job or day program while negative outcomes include having no programming or inappropriate programming. Research innovations include examining 1) both organizational and individual social networks and 2) how the quality of network relationships and beliefs about appropriate activities held by both families and agency staff influence transition choices. Through linking network data to outcomes six months after high school completion, the study shows how and why some connections are more effective than others."

The final example is 127 words and much clearer. The scientific sense is still there, with a 10 percent saving in word count over the original version. In the course of a 12- page proposal narrative, that's like giving yourself an extra page to explain your research. The final version is also written in plain language, but clearly links concepts back to their theoretical roots by using the scientific term social capital and appropriate references.

Hiring a Professional Editor

You may want to hire an editor to ensure your application is error-free. A professional can ensure your proposal says what you really mean. Editors-for-hire can provide these services:

- Copy editing or line editing, which includes correcting style; clarifying expression; making suggestions for structure; and ensuring proper use of gram- mar, diction and syntax. Professional editors can improve these fairly quickly if there are no underlying problems with the science.

- Content review. What appears to be a writing problem may actually be a content problem. These boil down to two kinds:

  1. You're not sure what you're really trying to say.
  2. There's a problem with the concept itself. You should be able to say: "This study was conducted this way and produced these results, with these caveats and limits."

Example: "There is evidence of the efficacy of cognitive-behavioral therapy in reducing chronic pain in some subsets of the population." This naturally leads the reader to ask a series of questions: Which subset? How were these isolated? What kinds of testing uncovered these results? How much was learned, and how much remains unknown? The structure of the improved paper can now be visualized.

Consider hiring an editor if:

- You don't have enough time to polish or hone your application. Or you've lost focus and will lose a lot of time trying to find it.
- You're not a very good writer. A professional grant writer can offer you form compositional structures that will allow readers to easily understand what you're saying.
- Many researchers are involved. The application can easily lose focus if the investigators can't agree. Sometimes a third party can step in and find ways to create a single vision.
- English isn't your first language.

However, it is important to be cautious and careful when selecting a professional writer. The last thing you need is someone who knows how to cut out language but doesn't know anything about your subject matter. Sometimes a researcher with grant writing expertise will use very specific language that will have meaning to reviewers but would look like jargon to cut out to a professional writer. While your proposal needs to be succinct, the word count is not the most important thing about your writing. If you hire a professional editor, be sure that person has a background in your field. Otherwise, they are likely to make changes that will change the meaning of your proposal. You should be the last decision maker in what your application says, not the professional editor.

11 SIMPLE MISTAKES THAT CAN DERAIL YOUR GRANT APPLICATION

Often, the simplest, most basic errors can hurt grant applicants the most. Here are 11 of them:

1. Failing to allocate enough time to write. Typically, you can assume you will need 120 hours to write, review and revise an NIH application for a three- to five-year grant. A smaller, non-governmental grant can take three or four months to complete. Bottom line: Overestimate the time you think you'll need, and plan all your timelines accordingly. Be sure to include adequate time for outside readers to review your writing. Remember, the last thing you want to do is anger your mentor or colleagues by asking them to review a long, complicated proposal in a few days.

2. Skipping the instructions. Do not bend, modify or get creative with them. Follow rules regarding font, font size, margins and word count. Pay attention to details on allowable budget expenses. When in doubt, contact the program officer.

3. Poor writing. Don't assume the reader understands your jargon and can follow the compelling rationale or breach the gaps in your logic. Lead the reviewer to logical and natural conclusions. Keep abbreviations, strange acronyms and jargon to a minimum.

4. Failing to edit. As mentioned previously, you should edit your proposal yourself and ask others for feedback.

5. Inadvertent plagiarism. The NIH runs all grant proposals through plagiarism programs. Before submitting yours, do the same. Programs include iThenticate, Plagiarism Detector and Copyscape. You can even enter sections of your proposal into a search engine to be sure you haven't inadvertently copied from someone else's research.

TIP:

Don't assume the reader understands your jargon and can follow the compelling rationale or breach the gaps in your logic.

6. Forgetting the responsible conduct of research plan. You are required to have one for all students (graduate or undergraduate) or postdoctoral researchers who receive a salary from your grant. This ensures appropriate training and oversight. Discuss your plan with your compliance office to be sure you have the right measures in place.

7. The reviewers did not find your central scientific question interesting. Arguably, the single most common reason for a grant receiving a low score is reviewers' perception that your central scientific question lacks significance. Reviewer uninterest in your question could stem from your failure to communicate its significance clearly, an overly narrow focus, or a lack of novelty and originality that suggests you are addressing a problem already solved.

    One way to test your proposal's significance is to provide a non-expert colleague with a three-sentence description. If he or she can appreciate why you are doing the work, then you are on the right track.

8. The preliminary data are weak and call into question your proposal's feasibility. Or there is an overly large gap between your hypothesis and your preliminary data.

9. The overall success of your project depends upon the outcome of a key component, which you have not performed. There is a natural tendency to organize research in a linear and sequential fashion. For a research grant, however, this strategy can be risky. If the succeeding aims all depend on a positive outcome of Aim One (which is yet unproven), your whole project depends on that first component's success.

10. The project's scope is too ambitious, with multiple hypotheses or rationales that pull the grant in disparate directions. This is called "spaghetti syndrome," in which every good hypothesis or research question in the PI's pantry is thrown at the problem. This approach rests on the assumption that reviewers will find   at least a few good ideas stuck on the proverbial wall, and this will raise their enthusiasm. In reality, this approach diminishes enthusiasm. It suggests a PI is unable to prioritize among the project's various facets, which can lead to an inefficient deployment of people and resources.

11. The PI or research team lacks the experience to carry out the proposed work. For first-time and early investigators, reviewers will assess training and accomplishments during the postdoctoral years. For more senior investigators, reviewers will look at past career experience and productivity. If a particular approach is unproven with respect to your team, the most reliable strategies are:

   a. Identifying and soliciting an outside collaborator with a published track record in the method

   b. Generating the preliminary data to remove doubts about your ability.

MAKE THESE FINAL CHECKS

Below is a list of some of the more common errors made by applicants, based on historical information accumulated by the NIH:

- Does the data universal numbering system number on the SF424 (R&R) cover form match the system for grants.gov and commons registration?

- Did you include the eRA commons ID in the credential field of the R&R senior/key person profile form for all PIs? This is critical to NIH's ability to post errors, warnings and the assembled application image in eRA commons.

- Did you include the organization name for all senior/key people listed on the R&R senior/key person profile form?

- Did you follow the page limits specified in the FOA and application guide?

- Did you use an allowable font type and size?

- Did you provide the correct type of submission, federal identifier and type of application information on the SF424 (R&R) cover form?

On initial submission, the type should be set to "application." For subsequent submissions, it should be set to "changed/corrected."

Changed/corrected applications sent in before the due date do not require a cover letter. Any application submitted after the due date must include one. For electronic submissions, the cover letter is a PDF attachment to the PHS 398 cover letter file component in the optional documents section.

There are nine application types you can use to identify the stages in a grant's life cycle. The type defines the procedures and specifies the documents required to process the award. You can only choose one.

1. New: A request for support of a project that has not been funded

2. Competing continuation: An appeal for an additional support period based on a previously funded project

3. Supplement: A solicitation for additional funds, either for the current operating year or for any future year, to cover increased costs (noncompeting) or to expand the scope of work (competing)

4. Extension: A request for additional time and/or funds beyond those previously awarded. These are typically limited to certain mechanisms, including Merit (R37), Developmental/Exploratory (R21/R33) and Fast-Track Small Business Grants SBIR/STTR (R42/R44). These grants do not compete for available funds.

5. Noncompeting grant progress report: An appeal to pay the next budget increment of a current award. This does not compete for available funds.

6. Change of institute or division: A request for NIH's acceptance of a change in business structure, such as successor-in-interest, name change or merger

7. Change of grantee or training institution: An appeal for support of a funded project to be transferred from one grantee or training institution to another

8. Change of institute or center: A noncompeting continuation to be transferred from one institute to another

9. Change of institute or center: A competing continuation that has been transferred from one institute to another

TIP:

NIH uses the HHS logo within the application guide to flag agency-specific instructions and clarifications for fields on federal wide forms. Pay special attention to the HHS logo, or you may miss key NIH requirements.

SUBMITTING THE APPLICATION

Typically, the authorized organization representative (AOR) will submit all application materials. A PI can submit materials with the AOR's approval, but NIH won't accept materials that have not been approved.

To submit your proposal, go to the grants.gov login page and enter your username and password. Once you are logged in, the application package will be automatically uploaded to the website. A confirmation screen appears once the upload is complete, and a grants.gov tracking number is provided. Keep this number for your records.

If everything is acceptable, no further action is necessary. The application will automatically move forward to the Division of Receipt and Referral in the Center for Scientific Review for processing.

On the other hand, if some part of the proposal was lost or did not transfer correctly during the submission process, the AOR can reject it and submit a changed/corrected application. In these cases, you should contact the eRA help desk to ensure the issues are addressed and corrected. Once you've rejected the proposal, follow the instructions for correcting errors, including the requirement for cover letters on late applications.

Also use the reject feature if you determine that warnings are applicable to your proposal and must be addressed now. Remember, warnings do not stop the application process. If a submission results in warnings (but no errors), it will automatically move forward after two weekdays. Work with your AOR/signing official to determine when the reject feature is appropriate.

You may find you need to submit supplementary or corrective material after your due date — for example, revised budget pages, updated biographical sketches, letters of recommendation or publications that have been accepted but not published. Acceptance of those materials is at the discretion of the NIH SRO. Be sure to send any additional documents as PDF attachments to emails.

You must submit additional materials to the SRO with the consent of your AOR, and the AOR should be copied on correspondence to the SRO.

Direct from NIH:

SHOULD YOU WITHDRAW THE APPLICATION?

There are two ways to stop the application from moving forward for peer review. You can withdraw it or you can simply reject the application image. Your application will undergo peer review as is unless your scientific review officer [SRO] allows you to send additional information or you have withdrawn it. You should consider withdrawing your application in the following circumstances:

- You feel the application is not up to snuff.
- You've run out of time for corrections and can't send additional data.

Remember that your goal is to impress your reviewers with the best possible application. Balance the severity of the problems with the amount of time you have left to correct them in the same review cycle. Compare that with the time lost if you wait for the next due date.

To withdraw your application from consideration, ask your organization to fax a signed letter to the Center for Scientific Review's Division of Receipt and Referral at 301-480-1987. Provide your NIH accession number.

If you plan to withdraw the application and resubmit for the same deadline, be careful. Once you no longer have an active application in the system, you will have the same disadvantages as anyone else who applies at the last minute. Allow at least two days to get your corrected application into the system.

CONCLUSION

Congratulations on your submission. You made the application deadline and there were no errors that could sidetrack your proposal's advancement towards review. Since you planned and executed the writing of your proposal well in advance, and are comfortable and confident on its content, there should be no reason for you to withdraw your application. ■

Chapter 9:
The NIH Application Review Process

This chapter outlines the National Institutes of Health's (NIH) review process. It describes how the Center for Scientific Review assesses applications and assigns them to review groups. It also explains how your application moves from an integrated review group (IRG) to a scientific review group (SRG) to an institute or center's advisory board or council.

You'll learn the four steps of the initial peer review process and how an SRG (otherwise known as a study section) rates your application. We describe how five criteria — Significance, Innovation, Approach, Investigators and Environment — are used to score your proposal. We explain the importance of Overall Impact, what percentiles mean, and how to interpret summary statements.

Also included in this chapter is information on tracking your application and steps to take once you've received a response from NIH. You'll learn about just-in-time information and how to resubmit your application if it is not funded the first time around.

NIH REVIEW PROCESS: A BRIEF OVERVIEW

Once you have submitted your application to NIH, it goes through a few levels of review. First, the Center for Scientific Review performs a cursory assessment, checking for errors that automatically disqualify an application.

If there are no errors, the center sends your proposal to the group of reviewers known as the IRG. From there, your application goes to a study section (SRG).

The SRG is composed of roughly 20 scientists, mostly non-federal, who have expertise in relevant disciplines and current research areas. The scientific review officer (SRO), who is an NIH staff member, staffs this group and appoints a few key reviewers to analyze your proposal in detail. The remaining members scan your application, reading only certain sections in depth.

NIMH has a separate review process with its own scientific panels that reviews 40 percent of the proposals accepted by NIMH. The remaining 60 percent are reviewed by the regular scientific review panels managed by the CSR. For applications reviewed by NIMH's internal panels, the CSR plays a role in managing the applications. The process looks the same to the applicant, although you may know that it is being reviewed by NIMH itself from the review panel assignment. To quote an NIMH program officer:

> *The SRO is involved in selection of which applications goes to which review group. The SRO helps avoid conflict of interest. They manage the review process. We [Program officers] know the journey the application takes for [applications reviewed by] our own [panels]. It's the same process as the regular review process. We may add someone from the community (clinician, provider, stakeholder). Our panels know the field better, gaps, etc. than [the reviewers who might be] on a CSR review panel.*

The study section votes and scores your application on the five review criteria: Significance, Innovation, Approach, Investigator(s) and Environment. The group

also evaluates your project's Overall Impact. The SRO compiles a summary statement that includes your application's scores as well as a more detailed critique.

After the SRG's assessment, your application goes to institute/center national advisory councils for review. Councils are composed of both scientists and lay members chosen for their expertise and activity relating to health and disease. Your application is only eligible for funding if both the study section and the institute/center advisory council recommend it.

NIH CHECKS YOUR APPLICATION

As soon as NIH receives your proposal, it goes to the Center for Scientific Review for a cursory review. The staff there makes sure it conforms with administrative and formatting requirements.

NIH calls this check a potential failure point because the agency may return your application without a peer review. This would happen if you:

- Didn't list other support
- Failed to include sufficient human subjects documentation, data, assurances, or other required documentation
- Omitted pre-approval documentation for submitting an application requesting $500,000 or more in direct costs for any one year
- Left out pre-approval documentation for an investigator-initiated clinical trial
- Didn't show documentation of approval for using select agents
- Included a detailed budget when it should have been a modular one
- Improperly formatted your application (wrong font size and margins)
- Submitted the forms in the wrong way — for example, emailing them instead of submitting through grants.gov
- Didn't meet the requirements of a request for applications or institute-specific program announcement, if responding to one of the initiatives
- Contacted a reviewer
- Submitted your application late

YOUR APPLICATION GETS AN NIH ID NUMBER

The Center for Scientific Review gives your application a unique identification number that looks like this: 1 R01 AI183723 02 A1 S1. Each part of the identifier provides a snippet of information about your application.

- The first number is the application type; for example, a new application is Type 1. This tells NIH whether your application is a new, renewal, noncompeting or other type of application.
- Next is the activity code, or the type of grant you've applied for; in your case, an R01 research grant.
- The next two-letter abbreviation is the institute code. For example, the National Institute of Allergies and Infectious Diseases code is AI.
- Next is the unique serial number Center for Scientific Review assigns.
- Then comes the suffix showing the support year for the grant.
- The final two are codes for a resubmission, supplement or fellowship institutional allowance.

In the eRA Commons, the website where you submit your application (https://commons.era.nih.gov/commons/), you'll see this NIH number. You'll also see the old grants.gov tracking number. But NIH staff will typically refer to your application using the NIH number.

YOUR APPLICATION IS ASSIGNED TO AN IRG, SRG AND INSTITUTE/CENTER

The Center for Scientific Review assigns your application to an IRG and then to a study section for the first round of peer review. It assigns institute/center advisory boards (sometimes more than one per application) for the next review level as well.

You can request review assignments in your cover letter. But keep in mind the center is not required to honor your requests. It may make different assignments based on NIH referral guidelines and workload factors.

There is not a one to one mapping between Institute assignment and scientific review assignment. Each review panel may review applications assigned to a range of institutes. In order to be reviewed, proposals also need to be accepted by an Institute. This is one of many reasons that it is important to have identified a program officer and Institute at the beginning of developing an application for NIH. You should name that program officer and Institute in your cover letter.

REMEMBER:

You can request review assignments in your cover letter. But keep in mind the CSR is not required to honor your requests.

Within three weeks of your submission deadline, your assignment should appear in the eRA Commons. Here's how to access it:

Log in to the commons to check. If you don't see your assignments within three weeks, call the eRA Commons Help Desk at 1-866-504-9552.

At first, you might not see the expected study section. Instead, that field may show the umbrella organization, the IRG. This will be updated over the next few days, when your application is assigned to the SRG that will actually perform the initial peer review.

If the Center for Scientific Review gives you an assignment you're not happy with, you can request a change.

After the funding agency receives your application, it is assigned to a program division using internal referral guidelines. The program officer, grants management specialist and SRO fields will be blank initially in the eRA Commons.

Call if You're Not Satisfied With an Assignment

Follow these steps if you are not happy with your study section or institute/center assignment:

1. Inform your SRO of the problem well before initial peer review begins. Speak up if a committee member has a conflict of interest or you feel the group doesn't have adequate expertise.
2. Check the Center for Scientific Review study section roster index to find an alternative.
3. Discuss the alternative you prefer with the chief of the IRG for your assigned study section. You can get his contact information from your SRO.
4. Fax a letter to the center at 301-480-1987 stating your reasons for requesting a change. Here is an example of an acceptable request and an unacceptable one:
   a. Acceptable: "I noted that my proposal [title] was assigned to study section X, which focuses on biomedical aspects of cancer research while my study focuses on the impact of federal policy on cancer incidences. Could you please consider instead assigning my application to study section Y, which consists of social scientists and policy scholars with expertise in health policy?"
   b. Not acceptable: "I don't want study section X due to lack of expertise Z."
5. If that does not resolve the problem, appeal to the Center for Scientific Review's director of receipt and referral by calling 301-435-0715.
6. Be sure to talk to your program officer about the situation.

Waiting for the next receipt date is often better than getting reviewed by the wrong study section. You also have grounds for an appeal if the group doesn't have the expertise required for an effective peer review and, as a result, the assessment turns out poorly.

SUBMITTING ADDITIONAL INFORMATION

TIP:

NIH policy allows you to submit new material up to 30 calendar days before the peer review meeting.

You may add certain information to your submitted application, even though it's sitting in the eRA Commons database waiting for review. But there are restrictions on what you can add, guidelines on how to add it, and a deadline you should know.

NIH policy allows you to submit new material up to 30 calendar days before the peer review meeting. But only material that results from "unforeseen administrative issues" is acceptable. This includes:

- **Relocation information.** If you accept a job at a new institution or a new position with your current organization, you can write a letter notifying NIH of that.

- **Issues from natural disasters.** For example, notify NIH if your community was hit by a hurricane and the organizations where you plan to conduct your research can not participate until they can rebuild. This may require new letters of support from CBOs who can participate and a change of venue with some modifications to the proposal to explain the new research sites.

- **Letters of support.** If you decide to change key personnel and add a collaborator, you may submit a letter of support from that person.

- **Biographical sketch changes.** If an investigator suddenly leaves or you hire new personnel, you can alter Biographical Sketches.

- **Articles.** If publications were in press when you turned in the application, but they've now been accepted, you want to let NIH know.

- **Budget revisions.** For example, say you require the same piece of equipment for overlapping grant proposals, and your other grant was funded. You can submit a budget revision removing that equipment from the proposal about to be reviewed.

The SRO will determine whether your information will be included with your application. Post-submission materials NIH will not accept include:

- Support letters that don't result from a key personnel change
- Updated Research Strategy or Specific Aims pages
- Late-breaking research findings.

These guidelines will apply to all unsolicited, investigator-initiated applications. There are exceptions, however, for certain Funding Opportunity Announcements, training grants and Requests for Applications.

Follow These 5 Steps

There are essentially five steps to the post-submission process.

1. Contact your institution's Sponsored Programs Office or Sponsored Research Office

2. Secure the NIH-required signature from the signing official at your institution. NIH won't accept materials that are sent without it.

3. Follow NIH guidelines for the pages you're submitting. For example, updates or changes to a Biographical Sketch or a budget will require a form page. If a form page is not needed, however, NIH guidelines indicate you must limit each letter or explanation to one page. Also remember to follow NIH policies regarding margins, paper size and font size.

4. Prepare a description of the material you're submitting. If you're sending data, as an exception to one of the grant mechanisms listed above, you should:

- Design a concise table or graph to represent the data.

- Succinctly describe the experiment's design, results and conclusions.

- Indicate the significance to the proposal.

- Note results that will add to the proposal's innovative nature.

- Use a bullet-point format.

- Include the grant number and title.

5. Send the post-submission material to the SRO. NIH prefers you send the information electronically as a PDF. You should include:

   - A note to the SRO with a brief description of your attachment

   - One or two sentences about why you are submitting it

   - The grant number and title

   - All post-submission materials in one email.

If the SRO accepts your material, it will be uploaded to eRA Commons. You'll be able to find it by checking the "Additions for Review" section of your application.

INITIAL PEER REVIEW

Direct from NIH:

Your application's most significant test is initial peer review. Your peers — successful scientists in your field and related ones — use the information in your application to assess the merit of the science you've proposed and your ability to get the work done. Peer review results in a numerical value indicating the reviewers' judgment of the likelihood that your project will have a powerful impact on its area of science. That number is the most important factor in determining your application's success.

How SRGs Operate

The SRG is made up of scientists who have expertise in relevant scientific disciplines and current research areas. Each study section is led by an SRO, who is a staff scientist with the NIH's Office of Extramural Research. The SRG also has a chair, who serves as moderator for discussing applications' scientific and technical merit and is a peer reviewer.

Study sections are typically composed of about 20 reviewers. It is their duty to:

- Declare conflicts of interest with specific applications following NIH guidance
- Receive access to the grant applications approximately six weeks prior to the peer review meeting
- Prepare a written critique (using review critique fillable templates) for each application assigned per the SRO, based on review criteria and judgment of merit
- Assign a numerical score to each review criterion

- Make recommendations concerning the scientific and technical merit of applications, in the form of final written comments and numerical scores
- Make recommendations concerning protections for human subjects; inclusion of women, minorities and children in clinical research; welfare of vertebrate animals; and other areas as applicable for the application
- Make recommendations concerning appropriateness of budget requests.

Federal officials who are not part of the review board are allowed to attend review meetings. But they must have advance approval from the responsible SRO. These individuals may provide programmatic or grants management input at the officer's discretion. Program officers are one type of federal official that can attend review meetings, but they often have no input in the review process.

The 20 people on the review panel will come from various disciplines and may include clinicians, advocates or policy makers. If your proposal is for a targeted RFA, the SRO may develop a separate review panel just for that RFA with input from the program officers managing the RFA competition regarding potential reviewers.

What SROs Do

Direct from NIH:

Your SRO does an initial check of your application to make sure the key parts are there. If you're responding to a request for applications, program staff will check to ensure it is responsive to the request for application.

Before sending your application to reviewers, SROs look at it more thoroughly to make sure it's complete, and they may contact you if anything is missing. If this happens, send in the information quickly so reviewers receive it well before the review.

The SRO ensures each application receives an objective and fair initial peer review, making certain all applicable laws, regulations and policies are followed. The officer performs the following tasks:

1. Analyzes application content and checks for completeness
2. Documents and manages conflicts of interest
3. Recruits qualified reviewers based on scientific and technical qualifications and other considerations, including:
   a. Authority in scientific field
   b. Dedication to high-quality, fair and objective reviews
   c. Ability to work collegially in a group setting
   d. Experience in research grant review
   e. Balanced representation
4. Assigns applications to reviewers for critique preparation and designation of individual criterion scores
5. Attends and oversees administrative and regulatory aspects of peer review meetings
6. Prepares summary statements for all applications reviewed

The SRO selects at least three reviewers to examine each proposal and report on it to the rest of the study section. Not all of these reviewers may be experts in your methods and exact topic. Usually the lead reviewer has the most expertise on your methods and/or topic. The other two reviewers would also have relevant expertise, but may include a practitioner, clinician or someone else who would not know all the intricacies of your field. For this reason, it is especially important to write for several audiences, including educated lay people who may not be familiar with the science in your field. These individuals are highly influential in how the SRG grades each application. In fact, for your grant to score well, all three must become enthusiastic advocates of your proposal.

The assigned reviewers are typically those panel members who are most familiar with your area of research. If none of the members have the necessary expertise, the SRO will find at least one ad hoc reviewer with the appropriate credentials.

REMEMBER:

The SRO selects at least three reviewers to examine each proposal and report on it to the rest of the study section.

In most cases, the primary reviewer will be best acquainted with your work and will take the lead in presenting your application to the panel. The second reviewer will likely be nearly as familiar, having published in the same field or a related one.

These two reviewers will scrutinize all aspects of your research plan carefully, taking into account significance, feasibility and innovation, as well as your qualifications to perform the proposed work. With their expertise, they are positioned to decide whether your planned studies will significantly advance the field, rather than merely provide incremental progress on an already well-characterized system.

The third reviewer, who is often called the "discussant," is usually different. He will probably not be an expert in your field but will have a general knowledge of it. For example, the discussant may have learned about your field by teaching certain aspects of it in a survey course. The discussant may also be a practitioner in the field of study. For this person, the crucial part of your proposal will often be the "Significance" section.

The discussant will look for details regarding specific ways your research, if successful, will affect fields other than your own. Consequently, the better you can establish that your findings will have important implications at large, the more likely this reviewer will appreciate your work's significance and convey enthusiasm for your research to the study section.

The three reviewers may well be the only people on the review panel who have read your entire proposal. Seasoned reviewers and program officers acknowledge that the other panelists who vote on your proposal may only have read the abstract and glanced at a few other sections. Remember that reviewers are very busy, active scientists who are doing many reviews in a short period of time. They are volunteers. This is why it is so important to be extra careful writing your abstract and write a clear, compelling story that will draw in readers. A regular NIH reviewer summarized the interaction between the three person review team that occurs before the panel meeting in the following way:

The lead reviewer really summarizes and does in-depth analysis. They all discuss pros and cons [of the proposal]. They go back and forth and talk about it. If lead reviewer doesn't like the grant, you're in real trouble. There is negotiation between the team of three. Each reviewer scores on the criteria and writes comments. They look at the criteria [which may be specific to this panel] to figure out their scores. [The review is] dependent on the level of the science. They focus on 12 pages, is it great design but no significance? Design and approach are critical. A lot of this focuses on who the team is. Not just one piece or another [leads to the final scores] it's a whole integrated process – need to have all the pieces together.

One of the myths for qualitative researchers is that they are up against review panels unfamiliar with qualitative research. While program officers and reviewers interviewed for this manual acknowledged that it is important to present your research questions in a form that looks like a hypothesis, all noted that there is increasing knowledge of qualitative methods. One program officer commented: "Several of the regular study sections have qualitative methods expertise. Sometimes qualitative reviewers are most brutal reviewers of qualitative research."

In the review panel meeting, the lead reviewer will summarize each proposal and the discussion about the proposal that has occurred among the three reviewers. Other reviewers on the team may add their comments. Then there is a general discussion and vote on each proposal.

BASIC LAYOUT OF INITIAL PEER REVIEW

The peer review process has four steps:

1. Applications are reviewed based on established criteria.
2. Assigned reviewers summarize their prepared critiques for the group.
3. The entire panel discusses the application.
4. Final scoring of Overall Impact/priority scores is conducted by private ballot.

After the SRO opens the meeting, the primary reviewer presents your application to the group. Those with conflicts of interest should have already left the room. The remaining individuals review applications in the order of their preliminary Overall Impact scores, which helps them calibrate final scores. This also helps reviewers gauge when it is appropriate to stop discussing applications, as they generally do not discuss about half of the applications.

At that point, the group decides if other applications merit discussion. They explore differences of opinion, interacting heavily during the discussion, which generally lasts 10 to 15 minutes. Other study section members ask the assigned reviewers questions and skim the application during the discussion.

Generally, once the group has found a fatal flaw everyone agrees to, they stop discussing the application. Examples of fatal flaws include not protecting the safety of lab workers or animals, proposing too much work for the award time, not recognizing a key paper in the field or including a factual inaccuracy.

Where possible, study sections evaluate applications from new and early-stage investigators before the more experienced researchers. That way, the SRGs review at least half of applications for new investigators, and NIH can meet its targets for funding them. Review materials are confidential, so reviewers are not allowed to divulge any information outside the meeting. At the end of the meeting, NIH staff collect and destroy all materials used in the review.

Most Reviewers Scan Each Application

Generally, only assigned reviewers will read your application before the review. Others mostly read just your Abstract, Significance and Specific Aims. SRGs receive dozens of applications for each meeting, totaling thousands of pages to read in a few weeks, and members have full-time jobs. They couldn't possibly read all applications in depth.

Keep in mind that all of the study section members will score your application, even though only a few will have read it in depth. That's why you write and organize your Specific Aims for both audiences. You must make a strong case for your research so the assigned reviewers can readily read, understand and explain your project to the group.

HOW REVIEWERS SCORE APPLICATIONS

Before the SRG meets to discuss the applications, each reviewer and discussant assigned to an application gives a separate score for the five criteria — Significance, Investigator(s), Innovation, Approach and Environment. In addition, they assign a preliminary Overall Impact score to an application. Applicants will receive a report or summary statement detailing the individual scores of the assigned reviewers and discussant(s), even if the full committee does not discuss the application.

Noncompetitive Applications Get a Streamlined Review

Direct from NIH:

NIH uses a process called "streamlining" so reviewers can focus on applications that have a chance of being funded. Review committees don't review any application the group unanimously feels is roughly in the bottom half of applications being reviewed at the meeting. That percentage varies by grant type as well as by study section. Because no institute funds 50% of applications assigned to it, there's no need to review the bottom half. Here is how streamlining works:

- One week before the study section meets, SROs ask members for a list of applications they feel should not be reviewed and prepare a combined list.
- If any reviewer disagrees with a call, the group will review that application.

Non-Numeric Scores

1. Not discussed (ND). Applications unanimously judged by the peer review committee to be less competitive are not discussed. These applications do not receive a numerical impact/priority score, but they do receive individual criterion scores. No set number of applications is discussed; in some meetings, the ND option may not be used.

2. Not recommended for further consideration (NRFC). A majority of reviewers must vote in favor of NRFC for an application to be designated as such. Members will vote for NRFC in the following scenarios:

   a. The application lacks significant and substantial merit.
   b. The project presents serious ethical problems regarding the protection of human subjects.
   c. The research poses serious ethical problems in the use of vertebrate animals, biohazards and/or select agents.

   NRFC-scored applications do not proceed to the second level of peer review (national advisory council/board) because they cannot be funded.

3. Other non-numeric scores
   a. Deferred (usually due to lack of sufficient information, quorum or to allegations of research misconduct)
   b. Abstention (used rarely)
   c. Conflict (score put in by a reviewer who is in conflict with the application)
   d. Not present

Competitive Applications: Five Criteria Determine the Score

The reviewers and discussant(s) assign scores for the five criteria related to your proposal's scientific and technical merit. The scores are based on the 1-to-9 scale. Your application does not necessarily need to be strong in all categories to

be judged likely to have major scientific impact. For instance, a project that is not necessarily innovative may be essential to advance a particular scientific field. Now, let us examine the five individual score criteria used to evaluate your grant proposal.

Significance

For this criterion, reviewers determine if your proposed project addresses an important problem or a critical barrier to progress in your field. They also examine how scientific knowledge, technical capability and/or clinical practice will be improved if you achieve your project's aims. And they seek to understand how successfully completing the proposal's aims will change the concepts, methods, technologies, treatments, services or preventive interventions that drive the particular field.

A senior social scientist who has reviewed for NIH for years and chaired review panels offered this advice on ways to achieve a strong significance score:

> *I think this is the part where people don't realize who is the audience. Do your homework on the audience for the proposal (peer reviewers, program officers, members of the Institute's council). Peer reviewers – have a substantial investment [in the field] and public acknowledgement of their expertise. [You need to present a] multilayered statement of why your project is important, you need the right stuff for the branch or division's council. Align with a congressional mandated program or issue. Two or three words in quotes from whatever was in the call for proposals or [Institute or NIH] priorities. If you can find blue ribbon, by partisan conclusions about cutting edge issues or approaches, include them in your discussion of significance. Build up layers of statements from program announcements or priorities that fit the priorities the Institute is mandated to do. One fatal flaw is citing low ranking lit. Don't cite articles from a 3rd rate qualitative journal or social action publications. A few of these are OK, but you need 1st tier journal citations.*

Investigator(s)

This criterion represents the PI's qualifications. If it involves early-stage or new investigators, reviewers want to see experience and training. If the researchers are established, the SRG will look for an ongoing record of accomplishments that have advanced the fields involved. And if the proposal includes collaborative or multiple PIs, investigators should have complementary and integrated expertise. They must also have a leadership approach, governance and organizational structure that is appropriate for the project.

Innovation

The study section wants to see that an application challenges and seeks to shift current research, public health, or clinical practice paradigms by using new interventions, instruments, theoretical concepts, approaches or methodologies. The SRG wants to ensure that these factors are new to one research field or new in a broad sense. And the reviewers look for refined, improved or new applications of interventions, instruments, theoretical concepts, approaches or methodologies.

Approach

Approach represents a proposal's overall strategy, methodology and analyses. Reviewers want to ensure these aspects are well-reasoned and appropriate for accomplishing your project's Specific Aims. Address any potential challenges, alternative strategies and benchmarks for success. If the project is in its early stages, the Approach should include a strategy to establish feasibility and manage any particularly risky aspects of the research. If the project involves clinical research, the Approach should delineate plans for protecting human subjects   from research risks and plans to include minorities, members of both genders and children. It should also include any justifications of the proposed scientific goals and research strategy.

Environment

Reviewers want to ensure that PIs will have the resources — the institutional support, equipment and other physical assets — they need to successfully complete the proposed research. Institutional support includes confirming that the PI and other researchers involved in the project will have the time in the form of course releases or other mechanisms to ensure sufficient research time. They will also want to know that you will have access to students to help with the research through service learning courses, graduate assistantships, work study students and so forth. These human resources are as important for a social and behavioral science proposal as office space, good libraries, and availability of data sets.

Additionally, the SRG wants to know if there are any unique features of the scientific environment, subject populations or collaborative arrangements that will benefit the project. For projects that are working in communities or medical institutions, the reviewers will want to know that you have already established connections with community based organizations or medical clinics that can provide the environment to do your research and help you find the right research participants.

Role of the Review Criteria

Direct from NIH:

Peer reviewers don't score applications strictly by the review criteria; rather, the criteria are gauges for assessing merit and feasibility. Your assigned reviewers give your application a score for each criterion as well as the whole application; other reviewers score just the whole application. It's important to understand how review criteria relate to your score:

- Overall impact and merit. A final score reflects a judgment of the likelihood of a project to have a powerful impact on its area of science.

- Ideal application. To a large extent, reviewers judge your application based on their ideal outstanding application in your field of science. This is similar to a dog show, where dogs are judged for "best of breed" and different breeds do not compete with each other. So there is not a one-to-one relationship between how your application measures up to the review criteria and your score.

- Usage varies. Adherence to the criteria varies by committee.

- Weight varies. An application does not need to be strong in all review criteria to get a high Overall Impact score, though all criteria can affect your score. Two examples: Reviewers may assign an exceptional score to a proposal for important work that is not innovative but is essential to move a field forward. An application with high significance may receive an outstanding Overall Impact score even if reviewers are less enthusiastic about the other criteria.

Assigning an Overall Impact Score

The Overall Impact reflects the SRG's assessment of the likelihood that your project will exert a sustained, powerful influence on the research field(s) involved based on the five review criteria. The study section arrives at an Overall Impact score by following these steps.

1. Before the meeting, the assigned reviewers score each criterion and determine a preliminary Overall Impact score.
2. The discussion may prompt them to change their initial score.
3. The SRG votes. Assigned reviewers enter their official scores for each criterion and an Overall Impact score on the vote sheet. The other members can see these and give an Overall Impact score (and usually have an option of scoring each criterion).

REMEMBER:

The Overall Impact reflects the SRG's assessment of the likelihood that your project will exert a sustained, powerful influence on the research field(s) involved based upon the five review criteria.

Overall Impact Scores Range From 1 to 9

The SRG uses the preliminary score to determine which applications the group will discuss in full. Each member's score reflects his evaluation of the Overall Impact the project likely will have on the research field(s) involved, rather than being a calculation of the reviewer's scores for each criterion.

The scoring system uses a nine-point scale. The Overall Impact score for each discussed application is determined by calculating the mean score from all the eligible members' impact/priority scores and multiplying the average by 10. The final Overall Impact score is reported in the summary statement.

Use the following table to understand Overall Impact scores:

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses
Minor weakness — An easily addressable weakness that does not substantially lessen impact			
Moderate weakness — A weakness that lessens impact			
Major weakness — A weakness that severely limits impact			

Percentiling

Your Overall Impact score will be expressed on your summary statement in a percentile. This is the approximate percentage of applications that received better Overall Impact scores from the SRG during the past year. Keep in mind that only a portion of all applications receive percentiles because different NIH Institute/ Centers assign them to different types of applications. And your summary statement will identify the base that NIH used to determine your percentile.

Direct from NIH:

For appropriate applications — certain activity codes or request for applications – scores will be percentiled to the appropriate base (e.g. study section base if the number of R01 applications > 25; CSR-all or IC-all base if <25). All percentiles are rounded to a whole number. Until a base has been established from three rounds of review, percentiles are based on less than three application rounds.

ADDITIONAL REVIEW CRITERIA

In addition to the five scored criteria and the Overall Impact, there are other aspects of your application reviewers consider. Depending on their applicability to the proposed research, the SRG will evaluate the following additional items while determining scientific and technical merit and the Overall Impact/priority score. But the study section does not assign the following elements a separate score:

- Protections for human subjects. This is for research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46. For more information, see Qualitative Research & IRB: A Comprehensive Guide for IRB Forms, Informed Consent, Writing IRB Applications and More https://principalinvestigators. org/product/qualitative-research-irb/

- Reviewers evaluate the justification for involving human subjects and the proposed protections from research risk according to the following five review criteria:

  - Risk to subjects
  - Adequacy of protection from risks
  - Potential benefits to the subjects and others
  - Importance of the knowledge to be gained
  - Data and safety monitoring for clinical trials.

- Inclusion of women, minorities and children. If your proposal involves clinical research, the committee will evaluate your application for inclusion of minorities and members of both genders, as well as whether it includes children as potential subjects. There is a federal law (Public Law 103-43) that requires women and minorities to be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate. Similarly, NIH requires that children — defined as those younger than 21 years of age — be involved in all human subjects research supported by the agency unless there are scientific or ethical reasons for excluding them.

- Biohazards. Reviewers assess your application to determine if any materials or procedures proposed are potentially hazardous to research personnel and/ or the environment and, if needed, determine whether adequate protection is proposed.

- Resubmission (A1). When reviewing a resubmission application, which was formerly known as an amended application, the review committee will examine the application as presented, taking into consideration the responses you made to comments from the previous scientific review group and changes made to the project. This will start with a careful review of your introductory statement responding to comments. This page is particularly important as it provides a guide to revisions in your proposal. They will look to see how you have revised your proposal to respond to concerns raised by the previous review. These changes should be marked in your proposal in some way. Remember that your resubmission will likely be reviewed by an entirely different team of reviewers, so while you need to respond to comments, you also need to ensure that the proposal meets the other criteria of a successful proposal. For more information on revising and resubmitting, see Revising and Resubmitting NIH Proposals https://principalinvestigators.org/product/revising-and-resubmitting-nih-proposals-guide/

- Renewal. When examining a renewal application, which was formerly called a competing continuation application, the reviewers will consider the progress you have made in the more recent funding period.

- Revision. For a revision application, which was once called a competing supplement application, the committee considers the appropriateness of the proposed expansion of the project's scope. If the revision relates to a specific line of investigation in the original application, the committee will consider whether your responses to comments from the previous SRG are adequate and whether any substantial changes are clearly evident.

There are also certain elements that, if applicable to your proposal, reviewers will consider, but again, they will not score them individually. These include:

- An application from a foreign organization. The SRG will assess whether the project will further research programs by using unusual talent, resources, populations, or environmental conditions that are either not readily available in the United States or augment existing U.S. resources. Reviewers generally do not comment on the foreign component of domestic applications as part of this consideration, but any remarks will appear with those about the application's Approach section.

- Select agents. The study section will assess the select agent(s) to be used in the proposed research; the registration status of all entities where select agent(s) will be used; the procedures for monitoring possession, use, and transfer of select agent(s); and plans for appropriate biosafety, biocontainment, and security of the select agent(s).

- Resource-sharing plans. Reviewers will comment on whether the three following plans — or the rationale for not sharing these resource types — are reasonable:

  - Data-sharing plan. Applications requesting more than $500,000 in direct costs in any year of the proposed research should include a data-sharing plan. Certain program announcements may request a data-sharing plan for all applications, regardless of the amount of direct costs.

- Budget and period support. Reviewers will consider whether your budget and requested period of support are fully justified and reasonable in relation to your proposed research.

SUMMARY STATEMENTS

Once the study section has scored your application, the SRO prepares a summary statement. The document includes bulleted critiques from your assigned reviewers, a brief summary of the discussion, your Overall Impact score, your percentile, the SRG's recommended budget, human and animal subjects codes, and any administrative comments.

If your summary statement has an issue with human subjects, animals, or biohazards, NIH will assign it a code that prevents your application from receiving an award. The agency can't give you funding until you resolve the issue, so contact your program officer immediately.

Note that a summary statement is not an exhaustive critique. It is not a teaching tool containing every point reviewers found to be problematic in your application. But you can use it to revise a fixable application, if necessary.

Frequently Asked Questions About Summary Statements

Direct from NIH:

Q. How have summary statements changed?
A. The order of the review criteria has changed: Investigator(s) and Approach swapped positions; the new order (for research applications) is Significance, Investigator(s), Innovation, Approach and Environment. A table at the beginning of each critique summarizes the reviewer's scores for each criterion.

Q. How are the criterion scores displayed in the summary statement?
A. Criterion scores are added automatically by the Internet-Assisted Review (IAR) system as a table at the beginning of each reviewer's critique.

Q. What if the scores in the table do not agree with scores that may have been entered with the written critique?

A. The scores that IAR inserts in the table are accepted as final. Reviewers are instructed not to enter scores with their critiques and that errant scores in the critiques may be removed in finalizing the summary statement.

If You Have Additional Questions

The first thing to do when you get your summary statement is contact your program officer. They can help you understand if your score is within the range for funding and what can be done if it is just below or at the line for funding. How many proposals get funded and the scores required for funding varies from year-to-year and Institute–by-Institute depending on funding levels, priorities, and other factors.

Depending on the Institute or Center, it may be possible to get an application that is just on the line for funding or just below if funded through the support of NIH staff. Your program officer will be the first person to help you if this is possible and can explain the chances for funding in these circumstances and the procedure to lobby for a borderline proposal to be funded. Remember that the program officer is your best hope in a situation like this one and it is important to listen to the program officer and develop a relationship so that they will champion your work.

If your application scored too low for funding, program officers can help you interpret your scores and decide whether you should revise and resubmit. Program officers have no role in the review process; in fact, you are not allowed to contact them while the proposal is being reviewed. But after your scores have been posted, their job is to help you figure out next steps. It is important to remember that the program officer is your friend in this process. One program officer commented: "Don't argue with us about the contents of summary statements, we didn't write them. You can get a new review if there is substantial bias."

You can contact the appropriate awarding component program official, whose name is in your summary statement, to ask any questions. The contact can:

- Discuss the review outcome of the application and give guidance
- Provide feedback and answers to any questions about the summary statement
- Explain the meaning of a numerical designation pertaining to human subjects or vertebrate animals in the summary statement
- Relay the funding status of an application

Direct from NIH:

Applicant investigators must not communicate directly with any review group member about an application either before or after the review. Failure to strictly observe this policy will create serious breaches of confidentiality and conflicts of interest in the peer review process. From the time of assignment to the time the review of your application is complete, applicant investigators must direct all questions to the SRO. This individual is in charge of the review group and is identified in the eRA Commons.

STRATEGY:

If problems are fixable, start revising quickly. If your application misses the payline or is not discussed and its faults are fixable, start revising as soon as you can, because you may not have much time to revise after you get the summary statement.

SECOND LEVEL OF REVIEW: INSTITUTE/CENTER ADVISORY COUNCIL OR BOARD

Once the SRG has weighed in on your application, the Institute/Center's advisory council or board performs a second review. The boards are made up of scientists from the extramural research community and public representatives who are approved by the U.S. Department of Health and Human Services. The President of the United States also appoints members for certain committees.

During this second review process, NIH staff examine applications, Overall Impact scores, percentile rankings and summary statements. They provide the advisory board/ council with a grant-funding plan. The board considers the Institute/ Center's goals before advising the director, and the director makes the final funding decision.

REMEMBER:

During the second review process, the advisory board/ council considers the institute/center's goals before advising the director, who makes the final decision.

Applications that do not fall within the current payline but are aligned with NIH's priorities are placed on the "select pay" list. NIH staff create this list, prioritize it, and present it to the advisory board. If there is money left over at the end of the funding cycle, these selected applications will be funded in the order listed.

The process of review by the Institute's advisory committee or council varies from Institute to Institute. If your project is within the general scores for funding or near them, contact your program officer to find out the process for the Institute that is sponsoring your applications. The process may also be different for RFAs or cross-cutting funding opportunities that involve several Institute or Centers. Here are the processes for four Institutes that fund a significant number of social and behavioral science proposals:

- **NIMH** and **NIDA** have a group process to decide what is funded. If an application has a score near the fundable range, but hits a priority and the critiques can be fixed pretty easily, then it is dependent on the program officer to pull out the proposal for further consideration. It is presented at an

internal meeting at the branch, and then it is taken up to senior leadership. Even if the application was reviewed and scored high it has to fit agency priorities. The Institutes won't fund an application if won't add to new knowledge. If it has a great score, but is duplicative of other ongoing research, it will be low program priority. The final decision to fund does not happen until after the council meeting and budget allocation. It can be 9 months between submitting an application and finding out what will be funded.

- **NICHD** funds in score order, funding applications above or at the payline. On rare occasions, if you have essentially the same score as another grant that is being considered for funding, but yours has been ranked below the payline and your project addresses a priority, the council may swap them. Council review mostly focuses on RFAs. Unless a branch wants to pull an application out to talk about as either a priority or not, R01s submitted through the regular review process will not be discussed by the council.

- **NCI** relies heavily on recommendations from within the Institute regarding which proposals to fund. Within each division, there are discussions about what to do with proposals and what to fund. Since there are probably several applications from a branch or division that score within the payline, the division needs to decide which applications to move forward. Each program officer puts forward a funding plan stating which proposals they want to fund, and then there is a discussion in the division. Program officers present to an in-house group of scientific readers and everyone decides on which applications move forward. When it comes in front of the advisory board, if there are questions, staff can champion for your proposal and respond to questions.

If your application receives an award, you will be working closely with the Institute/Center program officer on scientific and programmatic matters and a grants management officer regarding budgetary or administrative issues.

WHEN YOU CAN EXPECT TO HEAR BACK

Your scores will be available in the eRA Commons three business days after the review is complete. Your summary statement should appear there within three weeks, although it is usually available earlier for new investigators.

Tracking Your Application

Direct from NIH:

The eRA Commons provides a valuable resource for applicants and PIs to track an application throughout various phases of the grants process. Within the eRA Commons, the Status tab is where most of the tracking information is found.

1. Use eRA Commons to track status. eRA Commons provides the status of your grant application and allows you to review detailed information associated with your applications/grants.

    a. Log in to eRA Commons with your user name and password
    b. Click the Status tab on the blue navigation bar across the top of the screen
    c. Find the application/grant of interest
    d. Click on the application ID. The Status screen contains the most current status and relevant documents for that application/grant.

2. Watch for email notifications. Email notices are sent to notify the PI and/or signing official to check the eRA Commons for a change in status.

3. Tracking during Peer Review phase.

    a. Score and percentile. Following the review group meeting, any available score and percentile information can be found in the application information section of the Status screen.

    b. Summary statement. Approximately three weeks after the review meeting a full summary statement is available in the other relevant documents section.

4. Tracking during Pre-Award and Award phase.

    a. Just-in-time (JIT). Some application information (other support, institutional review board and/or Institutional Animal Care and Use Committee approval dates and human subjects education information) is requested just prior to a final award decision. If needed, NIH will send a request for this information.

    b. Notice of award (NoA). The NoA is the official grant award document notifying the grantee and others that an award has been made and stating the terms and conditions of the award. You will find a link to the NoA under the other relevant documents section of the Status screen. NoAs can also be automatically emailed to the grantee organization. Organizational officials can maintain an NoA email address in the eRA Commons institutional profile.

5. Tracking during Post-Award Management phase. Several post-award tasks can be managed through the eRA Commons.

    a. Electronic Streamlined Non-Competing Award Process (eSNAP). eSNAP allows extramural grantee institutions to submit an electronic version of a PHS 2590 progress report. This information is needed to receive a non-competing award. An eSNAP link is available under actions in your Status list of grants.

b. Closeout. Electronically submit required closeout documents including Final Status Report (FSR), Final Progress Report and Final Invention Statement. At the appropriate time, a Requires Closeout link is available under actions in your Status list of grants.

c. No-cost extension. You can extend the final budget period of the project one time for up to 12 months beyond the original expiration date on your NoA as long as no cost or scope change is involved. At the appropriate time, an Extension link is available under actions in your Status list of grants. This may be completed electronically up to one day prior to the end of the project period.

JUST-IN-TIME INFORMATION

NIH may request just-in-time information if your application scored roughly within the top 20 percent. Although you may not get funded, you should prepare this information anyway. Ensure it is accurate and current.

Notify NIH of any substantive changes to previously submitted just-in-time information up to the time of an award, including changes in PI or key personnel status, as well as the approval of human subjects protections (IRB).

Other support information is always just-in-time. The funding agency also requests any of the following documentation relevant to your research that you did not include in your application:

1. Human subjects
   a. Assurance number
   b. Certification of institutional review board approval of research plan
   c. Certification of human subjects education

Other Support Submission

As a just-in-time filing, you'll need to send a list of other financial support — existing funding you have and any you may gain from the current application. If you have no other source of aid, your funding agency will need a letter from your institution's business office stating that fact.

Have any support information ready well before the award is made. It should show the following:

- No other organization is supporting the research you outlined in your plan: scientific overlap.
- Your time is not committed more than 100 percent: commitment overlap.
- You have not requested funding for items paid for by another source: budgetary overlap.

End-of-Year Warning

Funding agencies may skip over your application if it comes up for funding at the very end of the fiscal year and your just-in-time submission is not ready.

Your institution's business office should submit other support and human subjects training information within two weeks of receiving a just-in-time notice. You don't need to sign this information because you have a signature assurance on file with your institution. Because institutional review board and institutional animal care and use committee certifications may take more than two weeks, your business official may submit these approvals at the earliest date possible.

Whether you send the certifications with your application or as a just-in-time filing they should be sent together. NIH prefers that your institution submit the documentation through the just-in-time feature of the eRA Commons in PDF format.

RESUBMISSION (A1)

Nearly every PI who submits a proposal to the NIH is denied the first time out. In fact, the estimated first-time rejection rate is around 90 percent. Fortunately, NIH allows resubmissions for R01 proposals, and an estimated 35-40 percent of resubmitted applications get funded. The trick is knowing how to revise your application in a way that improves your funding chances. For detailed discussion of revising and submitting your proposal, see *Revising and Resubmitting NIH Proposals* https://principalinvestigators.org/product/revising-and-resubmitting-nih-proposals-guide/

Is Resubmitting Worthwhile?

Before you begin revising your application, ask yourself if resubmitting is worth it. Will you be rewriting more than half of the proposal? If so, creating a new one might be a better use of your time.

Have you pursued the research and continued to gather results, or did you move on to something else? Revising and resubmitting takes time and commitment, so the research should be meaningful to you. You may want to start over with a different project, a different institute or program, and/or a new deadline.

Identify the Reasons for Rejection

If you decide to revise and resubmit your proposal, your first step is to identify the reason(s) for rejection. Carefully analyze the peer reviewers' summary statements. Talk to your program officer and ask for their interpretation of the comments. They often can provide inside insights on concerns raised by reviewers. You should also share the comments with your co-PIs, senior colleagues and your outside reader. They may see things in the comments that you have missed.

Read comments more than once so you can identify your application's specific weaknesses and strengths. Look for critiques mentioned multiple times. You will likely see a pattern of issues you need to address in your resubmission.

In a case study of 605 rejected NIH proposals, researchers found three areas that attributed to rejection the most:

1. **Approach: 73 percent**
2. **Problem: 58 percent**
3. **Investigator: 55 percent**

Other reasons included institutional setting, unrealistic budget requests, inadequate personnel, lack of PI time, unconvincing project and sloppy presentation.

Respond to Reviewers' Comments

You have no control over issues with your institution, and you can't bend administrative, regulatory or agency guidelines. But you can respond to reviewers' comments about your approach, problem, experience, budget requests, personnel, overall project and presentation.

If space permits, your resubmitted application should include a reply to each comment. Highlight your explanations and changes [in italics, brackets or boldface]. If you're making significant alterations in the text, say so in your introduction.

Tips for Resubmitting

Get second opinions. Once you receive your reviews, you should seek out colleagues for their feedback on the reviews. They can be particularly helpful in advising on resubmission and ways to resolve problems identified in the comments. The most important second opinion you get may be from your program officer; they will better be able to tell you if you have an innovative idea worth pursuing in a resubmission.

TIP:

If space permits, your resubmitted application should include a reply to each comment, and highlight your explanations and changes.

Provide sufficient evidence to justify your project. Include specific background data. Highlight compelling new data you gathered while waiting for the initial response, and cite newly published research papers. Ensure your outcomes/objectives are measurable, obtainable and specific. Be sure to connect your research to its impact on the field and create a clear budget narrative.

Your Personnel Statement. With some imagination and creativity, there are ways you can use this statement to increase your chances of successfully being awarded funds. Make sure to describe your experience related to the subject matter being proposed in the application. In so doing, you must strike a balance between describing accomplishments and appearing boastful.

Focus on your writing. Create a strong introduction that keeps reviewers engaged and sets your proposal's tone. Be sure to label the progression of ideas, and keep your narrative concise by writing in short sentences and paragraphs.

Familiarize yourself with review process changes. Take note of new requirements like page limit reductions, and adhere to them.

NIH Policy Change on Resubmitting Applications

The NIH still allows only one resubmission of an unfunded application (see NOT-OD-09-016 at http://grants.nih.gov/grants/guide/notice-files/NOT- OD-09-016.html), which must be submitted within 37 months of the new (A0) application (see NOT-OD-10-140 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-140.html). If the resubmission is not funded, the previous policy stated that the application had to substantially differ in both content and scope in order to be eligible for submission as a new application. However, for all application due dates after April 16, 2014, if your resubmission application (A1) was unsuccessful at receiving funding, you may now submit the same idea as a new (A0) application for the next appropriate new application due date (see NOT- OD-14-074 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html). This change in resubmission policy applies to applications submitted to all grant and cooperative agreement funding opportunities that allow resubmissions, including all fellowship, training, and career development awards.

REMEMBER:

It is important to read the initial RFA or program announcement you applied under carefully to see if there are any special rules regarding A1 resubmissions.

Direct from NIH:

http://grants.nih.gov/grants/policy/amendedapps.htm

Per NOT-OD-14-074 (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html), for application due dates after April 16, 2014:

•   following an unsuccessful resubmission (A1) application, applicants may submit the same idea as a new (A0) application for the next appropriate due date.

NIH will not assess the similarity of the science in the new (A0) application to any previously reviewed submission when accepting an application for review.

This policy applies to all NIH Funding Opportunity Announcements (FOAs) that allow resubmissions, including FOAs for research grants, the NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, Career Development Awards, Individual Fellowships, Institutional Training Grants, Resource Grants, Program Projects, and Center Grants.

NIH's policy for accepting overlapping applications remains in effect (see NOT-OD-09-100 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-100.html). The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not review:

- a new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- a resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- an application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html).

NIH will not accept a resubmission (A1) application that is submitted later than 37 months after submission of the new (A0) application that it follows (see NOT-OD-12-128 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-128.html and NOT-OD-10-140 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-140.html).

Applicants should check the individual FOA to determine whether resubmission applications are allowed. Resubmissions normally are not permitted for applications received in response to a Request for Applications (RFA) unless it is specified in the FOA, in which case only one resubmission will be permitted. Since an RFA often has special considerations of eligibility, scientific scope, and review criteria, unfunded applications to an RFA must be submitted as new applications to another FOA, using that FOA's target due date for new applications.

Similarly, a change of grant activity code (e.g., from an R01 to an R21 or from an R03 to an R01) usually involves a change of eligibility criteria, application characteristics, dollar limits, time limits, or review criteria. These applications also MUST be prepared as new applications. More information on these policies can be found in the NOT-OD-03-019 (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-019.html).

The Purpose of this Policy Change

The new policy allows for ideas that were unsuccessfully submitted as a resubmission to be presented in a new grant application without having to substantially redesign the content and scope of the project. This policy change from the requirement that previously reviewed applications be substantially redesigned in order to be accepted as a new application is in response to researcher's concerns that changing the scope to be accepted as new resulted in many meritorious research ideas being deemed ineligible for resubmission. It was argued that this previous policy was especially hard on new investigators, since finding new research directions can be quite difficult during this phase of their career. Likewise,

TIP:

The revised proposal requires a one page introduction that explains how the investigator has revised the grant.

REMEMBER:

Not counting the introduction, a revised proposal must keep to the same page limits as other proposals.

established investigators expressed concern about the need to redirect the research focus of ongoing projects in order to submit future NIH applications.

Resubmission of an idea as new means that the application will be considered without a connection to a previous submission. As such, the applicant will not provide an introduction to describe how this application has changed or specifically respond to previous reviewer critiques. During review, the reviewers will be instructed to evaluate the submission as a new idea, even if they have seen this project in prior cycles. While there may not be major changes to the research direction of these previously reviewed ideas, the NIH does expect that applicants will still take advantage of previous comments to bolster the application for each submission. Also, if you had an unsuccessful resubmission before this new policy was issued, this previously rejected A1 is now eligible for submission as a new A0 application.

TIP:

If you had an unsuccessful resubmission before this new policy was issued, this previously rejected A1 is now eligible for submission as a new A0 application.

What Does This Mean in Practice?

- You may now submit a new A0 following an unsuccessful new A0
- Unless you would like the opportunity to address reviewer comments directly, you do not have to resubmit as an A1
- The new resubmission policy does not limit the number of times an application may be submitted as new
- Following an unsuccessful A1, you can submit as an A0 having the same title if you wish; it is not a requirement that you change the title
- As a new submission, it will receive a new grant number
- You still need to have received your summary statement before you can submit an unsuccessful A1 as an A0

Keep in mind, these rules refer to grants submitted through a general program announcement, not necessarily requests for applications (RFA). Most RFAs, which are one time competitions to meet a specific need, do not allow resubmissions. If an investigator wants to resubmit an RFA with revisions under a regular program announcement, that would be considered a new proposal.

CONCLUSION

This final chapter describes the review process, from receipt of your application by the NIH to 'just in time' procedures in the event that an award may be made to you. The information that you can expect to receive, as well as the timing of when to anticipate this information becoming available, is also described. The NIH realizes that you spend a lot of time getting to this point and they strive to keep you up-to-date with you application's progress. Remember that the majority of applications received by the NIH are not awarded. So, if your application is not funded the first time around, shake off the initial disappointment, heed the reviewer comments, and submit again. ■

Your Notes:

Appendix A: Index

About the Author: Dr. Jo Anne Schneider

Dr. Jo Anne Schneider is currently an Associate Research Professor in Anthropology at George Washington University. She served as an American Association for the Advancement of Science (AAAS) Science and Technology Policy Fellow at NIH working with National Cancer Institute to translate research into practice (2003-2005). Dr. Schneider is an urban anthropologist focusing on the role of government, non-profits, and communities in inter-group relations, opportunity structures for marginalized populations (immigrants, refugees, people of color, people with disabilities, low income families), and social welfare and health policy creation and implementation. Her work consistently involves working with government, local institutions, community members and policy makers to develop applied research projects and translate research into policy and programs. She has an international reputation for developing interdisciplinary projects. Her most recent work focuses on the role of social capital in marginalized communities and the dynamics between government, nonprofits, and communities in implementing social welfare and health policy.